UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

DAVID CHRISTENSON and
ANNIKEN PROSSER,

Plaintiffs,

Case No. 20-cv-194

v.

ALEX AZAR, in his capacity as Secretary of the United States Department of Health and Human Services,

Defendant.

MEMORANDUM IN SUPPORT OF DEFENDANT'S CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

I. INTRODUCTION

Plaintiffs David Christenson and Anniken Prosser suffer from glioblastoma multiforme ("GBM"), an incurable form of brain cancer. This case arises from an Administrative Law Judge's denial of their respective claims for Medicare coverage of certain months of tumor treatment field therapy ("TTFT"),[1] which uses electric fields to prevent tumor growth. Plaintiffs raise a single issue on appeal: whether the Secretary of the Department of Health and Human Services (the "Secretary") is forever collaterally estopped from denying plaintiffs' TTFT claims because an ALJ allowed coverage for certain months of TTFT claims.

The doctrine of collateral estoppel does not, as plaintiffs assert, apply to these kinds of administrative decisions, and to do so would be inconsistent with the design of the Medicare

[1] As discussed below, plaintiffs are not financially responsible for paying for the TTFT claims at issue if Medicare does not cover it.

Ex. "2"

program, which handles 1.2 billion Medicare claims per year[2] and covers over 60 million Americans.[3] The United States cannot be estopped on the same terms as a private litigant, and the Supreme Court never upheld an assertion of offensive collateral estoppel against the United States. *Heckler v. Cmty. Health Servs. of Crawford Co., Inc.*, 467 U.S. 51, 60 (1984); *United States v. Mendoza*, 464 U.S. 154 (1984). Plaintiffs are asking that a series of non-precedential decisions from ALJs forever estop the Secretary from denying claims for TTFT treatment to these plaintiffs. In so arguing, plaintiffs rely on *Astoria Federal Savings and Loan Association v. Solimino*, 501 U.S. 104 (1991), which held that an administrative decision, regarding an age discrimination claim, did *not* have preclusive effect because to apply collateral estoppel would be against Congress' intent in enacting the relevant statute. Indeed, plaintiffs fail to cite any cases on point, yet the Seventh Circuit as well as the Fourth, Fifth, Ninth, and D.C. Circuits have followed the Supreme Court's reasoning and rejected similar attempts to bind federal agencies to non-precedential decisions in administrative appeals.

To permit collateral estoppel would interfere with the discretion and deference afforded to the Secretary to implement the Medicare statute, run contrary to the Medicare statute's presentment and channeling requirements, and conflict with the Appropriations Clause of the U.S. Constitution. Moreover, even if there was no bar to collateral estoppel, Plaintiffs have failed to meet all four required elements. The issues in the ALJ decisions are not the same because the coverage determinations are limited to specified time periods. The same issues were not actually

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[2] *See* What is a MAC?, https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/What-is-a-MAC (last visited April 27, 2020).

[3] *See* Medicare Enrollment Dashboard, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Dashboard/Medicare-Enrollment/Enrollment%20Dashboard.html (last visited April 27, 2020).

litigated because the ALJ decisions specify that they apply to only the specific claims for Medicare coverage before the tribunal. In addition, because of the limits on when the Secretary can appear in ALJ hearings, the Secretary did not have a full and fair opportunity to litigate the issues. Plaintiffs have forfeited any other issues for judicial review.[4] The Secretary respectfully requests summary judgment be granted in the Secretary's favor and that Plaintiffs' motion be denied.

II. STATUTORY AND REGULATORY FRAMEWORK

A. "Reasonable and Necessary" Medicare Expenses

Medicare is a federal health insurance program for the aged and disabled. *See* 42 U.S.C. § 1395 *et seq*. Original "fee-for-service" Medicare consists of two parts: Part A, 42 U.S.C. § 1395c *et seq.*, which pays for inpatient hospital and related post-hospital benefits, and Part B, 42 U.S.C. § 1395j *et seq.*, which provides a voluntary supplemental insurance program for payment of various other types of care, including coverage for certain types of durable medical equipment (DME) for qualified recipients. 42 U.S.C. §§ 1395k, 1395x(s)(6).

For a medical service to be covered by Medicare, it must fit within a benefit category established by the Medicare statute. 42 U.S.C. § 1395k. The various benefit categories available under Medicare Part B are further set forth in 42 C.F.R. part 410. Medicare coverage is also subject to 42 U.S.C. § 1395y(a)(1)(A), which excludes certain items from coverage. Under this section, "no payment may be made under . . . part B of this subchapter for any expenses incurred for items or services[] which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member . . . ." 42 U.S.C.

[4] Plaintiffs have forfeited any argument that the ALJ decisions were not supported by substantial evidence by failing to make the argument in their motion for summary judgment. In the event that Plaintiffs subsequently raise the issue and the Court determines the argument has not been forfeited, the Secretary reserves his right to brief those issues on the merits.

§ 1395y(a)(1)(A). Unless there is an exception, this bar applies "[n]othwithstanding any other provision" of the Medicare statute. *Id.* The Centers for Medicare & Medicaid Services (CMS), which administers the Medicare program for the Secretary, has historically interpreted "reasonable and necessary" to mean that an item or service must be safe and effective, medically necessary and appropriate, and not experimental in order to qualify for reimbursement. *See* Medicare Program Integrity Manual (MPIM) § 13.5.4.[5]

To administer the "reasonable and necessary" standard, the Secretary employs a range of tools, from formal regulations to informal manuals. In choosing among these options, the Secretary is not required to promulgate regulations or policies that, "either by default rule or by specification, address every conceivable question" that may arise. *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 96 (1995). The Secretary may articulate "reasonable and necessary" standards through formal regulations that have the force and effect of law throughout the administrative process. *See* 42 U.S.C. §§ 1395hh; 1395ff(a)(1). The Secretary may also issue National Coverage Determinations (NCDs) "with respect to whether or not a particular item or service is covered nationally." 42 U.S.C. § 1395ff(f)(1)(B); *see also* 42 C.F.R. §§ 400.202, 405.1060.

B. Enforcement of the "Reasonable and Necessary" Standard Through Local Coverage Determinations (LCDs)

The Secretary has delegated to CMS broad authority to determine whether Medicare covers particular medical services. *See* 42 U.S.C. §§ 1395y(a), 1395ff(a), (f). CMS, in turn, contracts with Medicare Administrative Contractors (MACs), such as CGS Administrators in this case, to

[5] The MPIM is available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf. The MPIM "is a compilation of guidelines which CMS issues to instruct Medicare contractors on how to conduct medical review of Medicare claims submitted by Medicare providers and suppliers for payment." *Erringer v. Thompson*, 371 F.3d 625, 628 (9th Cir. 2004).

administer certain day-to-day functions of the Medicare program. 42 U.S.C. § 1395kk-1. Consistent with controlling regulations and NCDs, a MAC makes coverage determinations, issues payments, and develops LCDs for the geographic area it serves, *see* 42 U.S.C. § 1395ff(f)(2)(B), in accordance with the reasonable and necessary provisions in 42 U.S.C. § 1395y(a)(1). *See* 42 U.S.C. §§ 1395kk-1(a)(4). An LCD is binding only on the contractor that issued it, and only at the initial stages of the Medicare claim review process, as opposed to later stages if a claimant should appeal a determination by a MAC. 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II).

In developing LCDs, such as the one at issue in this case, MACs follow guidance contained in the MPIM. The MPIM requires MACs to publish LCDs that specify when "an item or service is considered to be reasonable and necessary." MPIM § 13.5.4. MACs develop LCDs by considering medical literature, the advice of local medical societies and medical consultants, public comments, and comments from the provider community. MPIM §§ 13.2.3, 13.5.2.1, 13.5.3, 13.5.5; 66 Fed. Reg. 58,788, 58,788 (Nov. 23, 2001). MACs also follow detailed procedures for issuing new or substantively revised LCDs, including engaging in a comment-and-notice period, soliciting feedback and recommendations from the medical community, and presenting the policy in meetings of stakeholders. MPIM § 13.2.1.

New LCDs require both a notice period and a comment period. MPIM § 13.2.4.2. The MAC first issues a draft LCD and provides the public a minimum of 45 days to comment on it. LCDs are principally based upon "available evidence of general acceptance by the medical community, such as published original research in peer-reviewed medical journals, systematic reviews and meta-analyses, evidence-based consensus statements and clinical guidelines." MPIM § 13.5.3. After considering all of the comments and revising the LCD as needed, the contractor

publishes the final LCD, providing at least a 45-day notice period before the LCD goes into effect. *Id*. at § 13.2.6.

C. The LCD for TTFT Devices

As set forth in the administrative record, both plaintiffs have glioblastoma multiforme (GBM), a kind of brain tumor. AR 4225, 5389. In April 2011, the United States Food and Drug Administration approved the marketing of a tumor treatment field therapy (TTFT) device called NovoTTF-100A, later rebranded Optune. AR 293. This device is manufactured by Novocure, for the treatment of recurrent GBM. AR 293, 298–322. Three years later, following an open meeting and solicitation of public comments, in August 2014, the DME MACs issued the original LCD for TTFT. AR 133. "The DME MACs determined that, based on the strength and quality of the evidence available at that time, TTFT was not reasonable and necessary for the treatment of GBM." *Id.* The LCD in effect at the relevant time, *i.e.*, during the dates of service for the claims on appeal, remained substantively unchanged and stated that "Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary." AR 98.[6]

In 2018, Novocure requested that the DME MACs approve Medicare payment of TTFT for newly diagnosed GBM. AR 118, 124. Effective September 1, 2019, the LCD was revised to permit coverage for newly diagnosed GBM and continued coverage for newly diagnosed GBM beyond the first three months of therapy in certain circumstances.[7] Novocure was "extremely

[6] The previous LCD is available at: https://localcoverage.cms.gov/mcd_archive/view/lcd.aspx?lcdInfo=34823%3a12 (last visited April 27, 2020)

[7] The 2019 LCD is available at: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34823&ver=27&DocID=L34823&bc=gAAAAAgAAAAA& (last visited April 27, 2020).

pleased" with the 2019 LCD and notes that its coverage criteria "is generally similar to Optune's commercial coverage criteria for newly diagnosed GBM."[8]

D. Administrative Review Process for Medicare Claims

CMS, through its contractors, processes millions of Medicare claims each year. To ensure efficiency and economy, Congress has required that a multi-level administrative claims and appeals process be exhausted before a Medicare beneficiary may seek judicial review. 42 U.S.C. § 1395ff; *see also Heckler v. Ringer*, 466 U.S. 602, 627 (1984). As the statutory and regulatory framework establishes, a Medicare beneficiary who seeks to challenge a denial of coverage must first request a redetermination of the denial by a Medicare contractor. 42 U.S.C. § 1395ff(a)(3)(B)(i); 42 C.F.R. §§ 405.904(a)(2), 405.948. Next, the beneficiary may request reconsideration by a qualified independent contractor (QIC). 42 U.S.C. §§ 1395ff(c)(1), (2); 42 C.F.R. § 405.960. The QIC's panel members must have "sufficient medical, legal, and other expertise, including knowledge of the Medicare program." 42 C.F.R. § 405.968(c)(1); *see* 42 U.S.C. § 1395ff(b)(1)(A), 1395ff(c); 42 C.F.R. § 405.960. An LCD is not binding at this and at higher levels of appeal. 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II); 42 C.F.R. § 405.968(b). After reconsideration, the beneficiary may request a hearing before an administrative law judge (ALJ). *See* 42 U.S.C. § 1395ff(b)(1)(A); 42 C.F.R. § 405.1002. Last, the beneficiary may request that the Medicare Appeals Council, a division of the Departmental Appeals Board of the U.S. Department of Health and Human Services, review the ALJ's decision. 42 C.F.R. § 405.1100. The MAC's decision represents the final decision of the Secretary. 42 C.F.R. § 405.1130.

[8] *See* Medicare Releases Final Local Coverage Determination Providing Coverage of Optune® for Newly Diagnosed Glioblastoma, https://www.novocure.com/medicare-releases-final-local-coverage-determination-providing-coverage-of-optune-for-newly-diagnosed-glioblastoma/ (last visited April 27, 2020).

E. Advanced Beneficiary Notices

If Medicare coverage is denied, Medicare will nevertheless pay the claim if neither the supplier nor the beneficiary knew or could reasonably have been expected to know that the item would not be covered. 42 U.S.C. § 1395pp; 42 C.F.R. § 411.400(a). However, the supplier is expected to be familiar with Medicare laws, regulations, and policies. 42 C.F.R. § 411.406. If the supplier should reasonably have known a claim would not be covered, Medicare is not responsible. 42 C.F.R. § 411.400(a). The supplier can shift the risk of non-coverage to the beneficiary by providing him with advance written notice (called an "Advance Beneficiary Notice") of the specific reason why the item probably will not be covered. 42 C.F.R. § 411.404(b). As the ALJs found in the decisions on review, because Novocure did not require Plaintiffs to sign an Advance Beneficiary Notice, no matter the outcome of this case, they will not be financially responsible for the TTFT claims at issue. AR 74, 4284.

III. FACTUAL AND PROCEDURAL BACKGROUND

A. David Christenson

Plaintiff David Christenson was diagnosed with glioblastoma multiforme (GBM) in July 2015. AR 96. He was initially treated with chemotherapy, radiation, and surgery, but his GBM recurred. AR 96, 203. In January 2016, he was prescribed the use of the TFTT device and temozolomide as treatment for his recurrent GBM. AR 96, 4225. As of February 2017, he uses only the TFTT device. AR 96, 4227. An MRI in September 2018 showed that Mr. Christenson's condition is stable. AR 96, 203, 206. Novocure, the supplier of TFTT, rents the device to Mr. Christenson on a monthly basis. AR 189.

CGS Administrators, the Medicare Administrative Contractor responsible for processing these claims, denied coverage for TTFT claims dated November 13, 2018, December 3, 2018, and

January 3, 2019. AR 95, 210, 247–49. The denial was based on LCD 34823, which provides that TTFT is not covered because it is not reasonable and necessary. AR 4174. On March 11, 2019, CGS affirmed the denial on redetermination and found Novocure liable for the cost. AR 240–42. On appeal, the QIC also upheld the denial of the claims and found Novocure liable. AR 4167–4178. Novocure and counsel for the beneficiary appealed the denial to an ALJ on June 14, 2019. AR 169, 179.

ALJ Scott Watson held a hearing on August 28, 2019. AR 95; AR 4217. Counsel for the beneficiary and the clinical appeal specialist for Novocure appeared. AR 4221. Representatives of the Medicare Administrative Contractor did not participate. AR 95.

ALJ Watson issued a decision (1-8630709341) on September 12, 2019. *Id*. He held that Medicare Part B did not provide coverage for the TTFT for Mr. Christenson's recurrent GBM and that, as there was no Advanced Beneficiary Notice, Novocure was liable for the charges. AR 99. ALJ Watson explained that ALJs are "not bound by LCDs" but "substantial deference" is given to them if applicable to the case. AR 98. He continued that if an ALJ chooses to disregard an LCD, he "must explain the reasons why" and the decision "applies only to the specific claim being considered and does not have precedential effect." *Id*. ALJ Watson found LCD 34823 applicable, explaining that it addressed TTFT as a treatment for recurrent GBM such as Mr. Christenson's. AR 98. He further found the LCD should be applied to the claims at issue and that TTFT was not reasonable and necessary in this case. *Id.* He acknowledged that the treatment has been effective for Mr. Christenson, but determined that there was not sufficient evidence showing that the LCD was not applicable or should be disregarded. AR 98–99.

Counsel for Mr. Christenson and Novocure appealed the decision to the Medicare Appeals Council, arguing that the previous appeal decided in Mr. Christenson's favor precluded the

unfavorable result and including the prior decisions. AR 5, 61. The ALJ in decision 1-8285652321, decided April 2, 2019, declined to follow the LCD, relying on studies conducted after the LCD was promulgated showing that the treatment was effective. AR 11–18. The ALJ in combined decision 1-8416270832 and 1-8416229632, decided June 6, 2019, also departed from the LCD "under the specific facts of this appeal" because he determined that the evidence showed the treatment was safe and effective. AR 23–30.

The Council notified counsel on January 22, 2020, that it was unable to issue a decision within the regulatory time frame and therefore counsel could escalate review to the district court. AR 1. Mr. Christenson first sought review of ALJ Watson's decision in the District of Columbia, but re-filed in this court as the proper venue.

B. Anniken Prosser

Plaintiff Anniken Prosser was diagnosed with GBM in February 2016 after an MRI discovered a tumor. AR 5392. After surgery to remove the tumor she underwent chemoradiation therapy, followed by treatment of temozolomide and TTFT in June 2016. AR 5393. She began using only TTFT in April 2017. *Id*. Her MRIs in 2018 and 2019 show that her condition is stable. *Id.*

CGS Administrators denied coverage for claims dated January 16, 2018, February 16, 2018, March 16, 2018, and April 16, 2018, based on LCD 34823. AR 4310, 5138–41. On July 10, 2018, CGS affirmed the denial on redetermination and found Novocure liable for the cost. AR 5130–32. On appeal, the QIC also upheld the denial of the claims and found Novocure liable. AR 5367–71. Novocure and counsel for the beneficiary appealed the denial to an Administrative Law Judge. AR 4381–87.

ALJ Joseph Grow held a hearing on May 20, 2019. AR 5387. Counsel for the beneficiary and the clinical appeal specialist for Novocure appeared. *Id*. The ALJ issued a decision (1-8390277469) on June 19, 2019. AR 4310–15. He held that Medicare Part B did not cover the TTFT to treat Ms. Prosser's newly diagnosed GBM and that, as there was no Advanced Beneficiary Notice, Novocure was liable for the charges. AR 4314. ALJ Grow found that counsel's arguments amounted "to challenges to the underlying record upon which the LCD is based" which is a separate adjudicative process. *Id*. During the hearing, counsel for the beneficiary responded "yes" that she was challenging the LCD under the regulations that allow LCDs to be reviewed in a separate process. AR 5395. He explained that LCDs are afforded substantial deference such that an ALJ must explain his reasoning if he chose to disregard it. AR 4313. Thus, as the relevant LCD was still in effect, he afforded it substantial deference. AR 4313–14. He further noted that the Medicare Appeals Council, in four nonprecedential decisions, cited the relevant LCD in upholding denials of coverage for TTFT. AR 4313.

On July 12, 2019, counsel for Ms. Prosser and Novocure appealed the decision to the Medicare Appeals Council. AR 4268, 4293. They included other favorable ALJ decisions for Ms. Prosser and argued they precluded the unfavorable result.[9] AR 4238–62.

The Council notified counsel on January 22, 2020, that it was unable to issue a decision within the regulatory time frame and therefore counsel could escalate review to the district court as. AR 4232. Ms. Prosser first sought review of ALJ Grow's decision in the District of Columbia, but re-filed in this court as the proper venue.

[9] In ALJ decision 1-8380637906, decided *after* ALJ Grow's decision, on June 27, 2019, the ALJ declined to follow the LCD based on the medical literature provided during the hearing and Ms. Prosser's success with the treatment. AR 4238–52. In ALJ decision 1-8416188648, decided May 16, 2019, the ALJ declined to follow the LCD base on the medical literature showing it was safe and effective for treating Ms. Prosser's newly diagnosed GBM. AR 4254–62.

IV. STANDARD OF REVIEW

In reviewing an administrative decision regarding a claim for Medicare benefits, the court reviews the administrative record to determine if the decision is supported by substantial evidence and based on the correct legal standard. 42 U.S.C. § 405(g); *Wood v. Thompson*, 246 F.3d 1026, 1029 (7th Cir. 2011). Substantial evidence is "more than a scintilla" and means "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Wood*, 246 F.3d at 1029 (quoting *Kaputsa v. Sullivan*, 900 F.2d 94, 96 (7th Cir. 1989) (further citations omitted)); *see Martin v. Saul*, 950 F.3d 369, 373 (7th Cir. 2020). In reviewing a denial of Medicare coverage, the Seventh Circuit has cautioned that decisions "made within the context of an extremely technical and complex field" like Medicare are properly entrusted to the "specialized knowledge" of the Secretary. *Wilkins v. Sullivan*, 889 F.2d 135, 140 (7th Cir. 1989).

The court's review is also limited to the administrative record, which the Secretary is responsible for certifying and filing. 42 U.S.C. §§ 405(g), 1395ff(b)(1)(A) (explaining the Secretary shall file "a certified copy of the transcript of the record including the evidence upon which the findings and decision complained of are based"); *Luna v. Shalala*, 22 F.3d 687, 689 (7th Cir. 1994); *see Fed. Power Comm'n v. Transcon. Gas Pipe Line Corp.*, 423 U.S. 326, 331 (1976). The exhibits attached to Plaintiffs' motion for summary judgment should therefore not be considered, particularly as Plaintiffs' exhibits include a number of documents, at Exhibits H, J, L, and M, that were not before the ALJs and are not a part of the record.

V. ARGUMENT

Plaintiffs seek a "sentence four" remand, which allows the court to enter a judgment affirming, modifying, or reversing the Secretary's decision, arguing that the earlier favorable ALJ decisions preclude the unfavorable decisions in 1-8630709341 and 1-8390277469, and in any coverage decisions going forward. Pls. Br. *See* 42 U.S.C. § 405(g); *Melkonyan v. Sullivan*, 501

U.S. 89, 99–100 (1991). In asserting that collateral estoppel can and should apply to ALJ decisions, Plaintiffs ignore the principle that preclusion cannot apply to agency decisions when there is a statutory purpose to the contrary. *See Astoria*, 501 U.S. at 108. Application of offensive collateral estoppel in this case would interfere with the discretion and deference afforded to the Secretary to implement the Medicare statute, run contrary to the Medicare statute's presentment and channeling requirements, and conflict with the Appropriations Clause of the U.S. Constitution. Furthermore, the elements of collateral estoppel are not present and it would be unfair to apply collateral estoppel against the Secretary. Finally, even if collateral estoppel applied, it would have no force after the new LCD became effective September 1, 2019.

A. Collateral Estoppel is Inapplicable to Medicare Claim Appeals

Plaintiffs rely heavily on the Supreme Court's decision in *Astoria* to press its argument that the favorable ALJ decisions should have preclusive effect, but they omit that the Court held the agency decision in question had no preclusive effect. Pls. Br. at 3. 501 U.S. at 106. There the Court explained that agency decisions should not be given preclusive effect when there is a statute expressing a contrary intent on the issue of preclusion. *Id.* at 108. *See Duvall v. Atty. Gen. of U.S.*, 436 F.3d 382, 387-88 (3d Cir. 2006) (stating that collateral estoppel cannot be applied if it would "frustrate congressional intent or impede the effective functioning of the agency."). At issue in *Astoria* was whether, under the Age Discrimination in Employment Act, "the judicially unreviewed findings of a state administrative agency decision" precluded re-litigation in federal court. 501 U.S. at 106. The Court noted that the statute required plaintiffs to pursue their claims under state law first and that state administrative proceedings had to be concluded before bringing suit in federal court. *Id*. at 111. Therefore, the Court concluded, it was safe to assume "the

possibility of federal consideration after state agencies have finished theirs." *Id*. If the state agency decision was given preclusive effect, the "federal proceedings would be strictly *pro forma*." *Id*.

Plaintiffs rely on several other cases for the assertion that collateral estoppel should apply to unreviewed ALJ decisions denying Medicare benefits, but they are inapposite. Pls. Br. 3–4. *B & B Hardware, Inc. v. Hargis Industries*, 575 U.S. 138 (2015), involved private parties, and the Court did not consider whether the federal government may be bound by administrative decisions. *Continental Can Co. v. Marshall*, 603 F.2d 590 (7th Cir. 1979) was decided well before *Astoria*, and therefore fails to perform the required analysis of whether there was a statute prohibiting collateral estoppel. *See B & B Hardware*, 575 U.S. at 148 (applying *Astoria*'s rule that issue preclusion cannot be applied if there is a statute preventing it). *Bowen v. United States*, 570 F.2d 1311, 1319–20 (7th Cir. 1978), was decided pursuant to Indiana's collateral estoppel law and, in contrast to the statutes in this case, Indiana law specifically stated that a federal administrative agency decision finding violations of air safety rules also constituted a state law violation because the state law incorporated the federal standard. In effect, the statute required collateral estoppel rather than prohibiting it. The court in *C & N Corporation v. Kane*, 953 F.Supp.2d 903 (E.D. Wisc. 2013), like *B & B Hardware*, 575 U.S. 138, did not consider whether the federal government may be bound by administrative decisions; it only considered whether private parties could be bound. Finally, the Supreme Court later explicitly held in *B & B Hardware* that the type of administrative decision at issue in *C & N Corporation* could be preclusive only because the Lanham Act did not prohibit it. 575 U.S. 138 (2015). Significantly, Plaintiffs have cited no previous case in which collateral estoppel was applied to a Medicare coverage determination.

1. *Federal regulations provide that ALJ decisions do not bind the Secretary in future cases.*

The Medicare statute and regulations bar the application of collateral estoppel to ALJ decisions. In fact, the Medicare regulations sharply distinguish between a narrow category of precedential decisions that are binding on future administrative appeals and the remainder of nonprecedential decisions that are not binding. In Medicare coverage cases, only Council-level decisions have the potential to become precedential, which occurs only if they are so designated by the Chair of the Departmental Appeals Board. 42 C.F.R. § 401.109. Council decisions designated as precedential must be made available to the public, with personally identifiable information removed, and notice of precedential decisions must be published in the Federal Register. 42 C.F.R. § 401.109(b). That decision is then given "precedential effect" and is binding on "all HHS components that adjudicate matters under the jurisdiction of CMS." *Id.* § 401.109(c).[10] The term "precedential effect" means that the Council's:

> (1) Legal analysis and interpretation of a Medicare authority or provision is binding and must be followed in future determinations and appeals in which the same authority or provision applies and is still in effect; and
>
> (2) Factual findings are binding and must be applied to future determinations and appeals involving the same parties if the relevant facts are the same and evidence is presented that the underlying factual circumstances have not changed since the issuance of the precedential final decision.

Id. § 401.109(d). Accordingly, the term "precedential effect" is synonymous with a decision having binding or preclusive effect. It is undisputed that no Council decision, much less one designated as precedential, has favorably decided Plaintiffs' claims.

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[10] HHS is the United States Department of Health and Human Services.

The regulations governing LCDs further support that the ALJ decisions are nonbinding and therefore collateral estoppel does not apply. Plaintiffs' collateral estoppel argument relies upon a favorable ALJ decision that departed from the LCD when approving TTFT treatment.[11] But in this circumstance, governing regulations provide that an ALJ's decision to depart from an LCD "applies only to the specific claim being considered and does not have precedential effect." 42 C.F.R. § 405.1062(b); 70 Fed. Reg. 11420, 11458 (Mar. 8, 2005) ("[T]he ALJ or [Council] may decline to follow a policy in a particular case, but must explain the reason why the policy was not followed. These decisions apply only for purposes of the appeal in question, and do not have precedential effect."). The regulations re-affirm that only "[p]recedential decisions designated by the Chair of the Departmental Appeals Board in accordance with § 401.109 of this chapter, are binding . . . ." 42 C.F.R. § 405.1063(c). Indeed, ALJ decisions are not even binding on lower levels of administrative review, such as the QIC second level of review. *See* 42 C.F.R. § 405.968(b) (omitting ALJ decisions among the rulings that bind the QIC).

Giving preclusive effect to ALJ decisions is also contrary to the Medicare statute, which provides that the Council must "review the case de novo." 42 U.S.C. § 1395ff(d)(2)(B); *see Porzecanski v. Azar*, 943 F.3d 472, 477 (D.C. Cir. 2019) ("Because the review generally binds only the parties unless specifically designated as precedential, a favorable determination in one proceeding does not ensure that future claims will be approved.") (citing 42 C.F.R. §§ 401.109, 405.1130, 405.1048). If a favorable ALJ ruling collaterally estopped the Council from denying a beneficiary's claim for the same treatment, the Council could not perform a de novo review; instead, the Council would be bound to accept the ALJ's conclusions. *See Almy v. Sebelius*, 679

[11] ALJs are not bound by LCDs, but are required to afford them "substantial deference." 42 C.F.R. § 405.1062(a). ALJs are not authorized to "set aside or review the validity of an . . . LCD for purposes of a claim appeal." *Id.* § 405.1062(c).

F.3d 297, 310 (4th Cir. 2012) (concluding that the Council's obligation to undertake "de novo" review was "incompatible with [plaintiff's] proffered notion that the [Council] is somehow obligated to defer to the outcomes of prior decisions below").

This is in line with the guidance from The Restatement (Second) of Judgments § 83 (1982)[12] that:

> (4) An adjudicative determination of an issue by an administrative tribunal does not preclude relitigation of that issue in another tribunal if according preclusive effect to determination of the issue would be incompatible with a legislative policy that:
>
> > (a) The determination of the tribunal adjudicating the issue is not to be accorded conclusive effect in subsequent proceedings; or
> >
> > (b) The tribunal in which the issue subsequently arises be free to make an independent determination of the issue in question.

Medicare regulations clearly state ALJ decisions are not to be accorded conclusive effect as they are non-precedential, and the Council's de novo review means it is free to make an independent determination. Accordingly, the Medicare statutes and regulations bar the application of collateral estoppel to the ALJ decisions.

2. *Applying collateral estoppel would interfere with the discretion and deference afforded to the Secretary to implement the Medicare statute.*

If ALJ decisions were to be deemed binding, this ruling would run contrary to the deference and discretion afforded to the Secretary to implement the Medicare statute, particularly as pertains to the "reasonable and necessary" standard for coverage of items and services furnished to program beneficiaries. *See Wilkins,* 889 F.2d at 140 (in discussing review of denial of Medicare benefits, court said "It is precisely this type of decision—made within the context of an extremely technical and complex field—that courts should leave in the hands of expert administrators. . . . Congress

[12] The Supreme Court has noted it "regularly turns" to this Restatement for guidance on issue preclusion. *B&B Hardware v. Hargis Indus.*, 575 U.S. 138, 148 (2015).

delegated these difficult decisions to agencies that have developed specialized knowledge.") "[T]he choice made between proceeding by general rule or by individual, *ad hoc* litigation is one that lies primarily in the informed discretion of the administrative agency." *SEC v. Chenery Corp.*, 332 U.S. 194, 203 (1947). The Medicare statute and regulations preserve "this discretion for the Secretary, leaving it to her judgment whether to proceed by implementing an NCD, by allowing regional contractors to adopt an LCD, or by deciding individual cases through the adjudicative process." *Almy*, 679 F.3d at 303. The Supreme Court has foreclosed arguments that interfere with this discretion, holding that "[t]he Secretary's decision as to whether a particular medical service is 'reasonable and necessary' and the means by which she implements her decision, whether by promulgating a generally applicable rule or by allowing individual adjudication, are clearly discretionary decisions." *Ringer*, 466 U.S. at 617; *see also Guernsey Mem'l Hosp.*, 514 U.S. at 97 ("The Secretary's mode of determining benefits by both rulemaking and adjudication is, in our view, a proper exercise of her statutory mandate.").

As noted above, the Medicare regulations designate ALJ decisions as non-binding and non-precedential, which allows individual adjudication over Part B claims. Generally speaking, this inures to the benefit of Medicare beneficiaries, who, even after repeated denials of similar claims, have the right to de novo review of any subsequent claims. The application of collateral estoppel would be fundamentally inconsistent with individual adjudication of Part B claims. In Plaintiffs' view, once a claim for benefits is approved, the Secretary would be estopped from ever denying a claim for the same treatment. Pls. Br. at 18. Individual adjudication would be impossible, because the earliest-in-time ALJ ruling would forever bind the Secretary. Accordingly, it is within the Secretary's discretion *not* to be bound by ALJ rulings. *See generally Ringer*, 466 U.S. at 607–08 (distinguishing between ALJ and Council-level decisions that "applied only to the claimants

involved in that case and [were] not to be cited as precedent in future cases" and a subsequent formal administrative ruling by the Secretary that bound ALJs and the Council).

Here, the Secretary's decision that ALJ decisions are non-binding and non-precedential is expressed in the plain, unambiguous language of the applicable law and regulations. *See Avalon Place Trinity*, DAB No. 2819, at 13 (2017) ("An unappealed ALJ decision [does not set] a precedent binding on ALJs or the Board. When the *Board* has not reviewed the ALJ decision, the *Board* has not issued a decision in that case. Regardless of whether an ALJ decision was appealed to the Board, an ALJ decision is not precedential and does not bind the Board, and is relevant in later cases only to the extent its reasoning is on point and persuasive.") (italics in original), *aff'd*, *Avalon Place Trinity v. HHS*, 761 F. App'x 407 (5th Cir. Mar. 4, 2019). Because giving preclusive effect to ALJ rulings would contravene the Medicare regulations, the Court should decline to apply collateral estoppel here.

While Plaintiffs fails to cite any cases on point,[13] this Circuit as well as the Fourth, Fifth, Ninth, and D.C. Circuits have each rejected similar attempts to bind federal agencies to non-precedential decisions in lower-level administrative appeals. *See Abraham Memorial Hosp. v. Sebelius*, 698 F.3d 536, 556 (7th Cir. 2012) ("The handful of prior Board decisions the Hospitals rely upon to purportedly show HHS's long-standing policy are not determinative. Our precedent

[13] Plaintiffs' reliance on the unpublished decision in *Brewster v. Barnhart*, 145 F. App'x 542 (6th Cir. 2005) is misplaced. Pl. Br. at 4. The court found that, under circumstances unique to Social Security disability appeals, an applicant (not the government) was bound by an ALJ's earlier finding concerning the exertion level of the applicant's past work. *Id.* at 546–48. Plaintiffs' additional citation, Pl. Br. at 4, to a case concerning the unique circumstances of immigration appeals is similarly unhelpful. *Islam v. U.S. D.H.S.*, 136 F. Supp. 3d 1088 (N.D. Cal. 2015). Among other things, unlike the Medicare statute and regulations' prohibition on collateral estoppel here, the *Islam* court determined that the Immigration and Nationality Act permitted collateral estoppel of issues decided by an Immigration Judge in granting asylum. *Id.* at 1093–94. Additionally, unlike here, the other elements of collateral estoppel were actually met in *Islam*. *Id.* at 1091–93.

instructs that Board decisions are not the decisions of the Secretary or her Administrator and are not authoritative."); *Homemakers North Shore, Inc. v. Bowen*, 832 F.2d 408, 413 (7th Cir. 1987) ("'The Secretary's position' is the position of the Department as an entity, and the fact that people in the chain of command have expressed divergent views does not diminish the effect of the agency's resolution of those disputes. An inconsistent administrative position means flipflops by the agency over time, rather than reversals within the bureaucratic pyramid.").

In *Almy*, plaintiff asserted that Council decisions denying coverage for a medical device created a policy of denying treatment for that device. 679 F.3d at 299. The Fourth Circuit disagreed, noting that "[t]he Secretary's own regulations make clear that any policy implications in an adjudication do not have precedential effect. . . . The purported 'policy' in this case is nothing more than the accretion of individual decisions finding that the [device] does not meet the statutory requirements for coverage." *Id.* at 303 (citing 42 C.F.R. § 405.1062). The Court noted that Congress gave the Secretary discretion to "decide how to deal with hundreds of millions of Part B claims for coverage of thousands of devices every year." *Id.* at 304. Likewise, this court should reject Plaintiffs' attempt to elevate nonprecedential ALJ opinions into binding coverage rules, which would "stultify the administrative process." *Id.* (quoting *Chenery*, 332 U.S. at 202).

In *Almy*, the Court noted that other circuits have concluded that "[t]here is no authority for the proposition that a lower component of a government agency may bind the decision making of the highest level . . . [E]ven if these cases were found to evince internal inconsistency at a subordinate level, the [agency] itself would not be acting inconsistently." *Id.* at 310 (quoting *Community Care Found. v. Thompson*, 318 F.3d 219, 227 (D.C. Cir. 2003)). Along the same lines, the D.C. Circuit has emphasized its "well-established view that an agency is not bound by the actions of its staff if the agency has not endorsed those actions." *Comcast Corp. v. FCC*, 526 F.3d

763, 769 (D.C. Cir. 2008) (citing cases). Instead, "a definitive and binding statement on behalf of the agency must come from a source with the authority to bind the agency." *Devon Energy Corp. v. Kempthorne*, 551 F.3d 1030, 1040 (D.C. Cir. 2008); *see, e.g.*, *Freeman v. U.S. Dep't of the Interior*, 37 F. Supp. 3d 313, 344–45 (D.D.C. 2014) (finding that "unappealed" ALJ rulings could not estop the United States because such rulings were not binding on the agency or even on other ALJs and noting that the lack of appeal did not "elevate them to the level of a binding final agency action").

The Ninth Circuit explicitly adopted the reasoning in *Almy*, reversing a district court decision that "incorrectly measured agency inconsistency across" ALJ decisions. *Int'l Rehab. Sci. Inc. v. Sebelius*, 688 F.3d 994, 1001 (9th Cir. 2012); *see also County of Los Angeles v. Leavitt*, 521 F.3d 1073, 1079 (9th Cir. 2008) (noting that "intermediary interpretations are not binding on the Secretary, who alone makes policy"). The Fifth Circuit reached the same conclusion. *See Homan & Crimen, Inc. v. Harris*, 626 F.2d 1201, 1205 (5th Cir. 1980) ("[T]he decision of the [Provider Reimbursement Review Board] carries no more weight on review by the Secretary than any other interim decision made along the way in an agency where the ultimate decision of the agency is controlling.").

In sum, "Congress has delegated broad authority to the Secretary to determine when a device is reasonable and necessary, as well as broad authority to select the procedures used for making that determination. The decisions of local contractors cannot deprive her of that discretion, any more than the diverse decisions of district courts or courts of appeals throughout the country could bind the Supreme Court." *Almy*, 679 F.3d at 311. The doctrine of collateral estoppel cannot transform an ALJ ruling from what it is—a decision by an intermediate-level tribunal that is only

binding in a single case—to what it is not, an officially binding statement of policy by the Secretary. To do so would be contrary to the Medicare statute and regulations.

3. *Collateral estoppel is contrary to the Medicare statute's presentment and channeling requirements*

To the extent that Plaintiffs seek to have the Secretary collaterally estopped as to future claims for TTFT, the D.C. Circuit in *Porzecanski* recently held that the Medicare statute prohibits a Medicare beneficiary from obtaining "prospective equitable relief mandating that HHS recognize his treatment as a covered Medicare benefit in all future claim determinations." 943 F.3d at 475.

The facts in *Porzecanksi* are similar to those in the instant case. Porzecanski suffered from a rare, life-threatening condition with no known cure and started on an experimental regimen of a biological product. *Id.* at 476. At the time, there was a dearth of scientific testing supporting the product for plaintiff's symptoms; nonetheless, during the course of plaintiff's treatment, the product came to be considered the best available treatment. *Id.* After beginning treatment, Porzecanski remained symptom-free and his physicians recommended that he continue the monthly treatment indefinitely. *Id.* at 476–77. After one of his claims was denied at the ALJ level and the Council did not render a decision within the required time frame, plaintiff filed in federal court. *Id.* at 477. While the federal case was pending, plaintiff continued to submit monthly Medicare claims, which were approved by a QIC or ALJ. *Id.* On appeal of his denied claim, plaintiff sought declaratory and injunctive relief confirming his entitlement to Medicare coverage for the product and requiring the Secretary to provide Medicare benefits. *Id.*

The D.C. Circuit held that plaintiff could not "satisfy § 405(g)'s presentment requirement with respect to future claims because those claims have not yet arisen." *Id.* at 482. Because Medicare claims can only be filed after the medical service has been furnished, and section 405(g) requires appeals from "decision[s]" of the Secretary, the presentment requirement could not be

met: "[T]he Secretary has not decided [plaintiff's] future claims because – to state the obvious – none has been submitted." *Id.*

The court also rejected plaintiff's request to preclude the Secretary from concluding that the claims on appeal were not covered by Medicare and were not medically necessary—the same relief that Plaintiffs seek here. *Id.* at 482 (finding plaintiff's "strained position" to be "at odds with Supreme Court precedent."). In support, the D.C. Circuit relied on two Supreme Court decisions: *Ringer* and *Illinois Council*. In *Ringer*, "the Court held that § 405(g) barred a patient from obtaining declaratory and injunctive relief compelling the Secretary to conclude that his future surgery was 'reasonable and necessary' under the Medicare Act." *Id.* (citing 466 U.S. at 620–21). Although the patient sought equitable relief, it was "essentially one requesting the payment of benefits." *Id.* (quoting 466 U.S. at 620). Any claim seeking to establish a right of future payments constitutes a "claim arising under" the Medicare Act. *Id.* (citing 466 U.S. at 621). Likewise, in *Illinois Council*, the Court again declared that a "claim for future benefits is a § 405(h) claim" and that "all aspects" of any future claim "must be channeled through the administrative process." *Id.* (citing 529 U.S. at 12).

The D.C. Circuit thus concluded, "*Ringer* and *Illinois Council* directly foreclose [plaintiff's] attempt to recast the requested relief as anything other than a claim for future benefits." *Id.* at 483. Likewise, Plaintiffs' assertion that the Secretary is estopped from denying their future claims for TTFT treatment "runs headlong into the Supreme Court's instruction that 'all aspects' of a claim be first channeled through the agency." *Id.* (quoting *Illinois Council*, 529 U.S. at 12). Plaintiffs cannot leverage a favorable ALJ decision to estop the Secretary from denying "future claims for the same reasons." *Id.* at 483–84.

4. *Collateral estoppel is contrary to the Appropriations Clause of the U.S. Constitution*

The Appropriations Clause of the Constitution, Art. I, § 9, cl. 7, provides that: "No Money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law." In *Office of Personnel Management v. Richmond*, 496 U.S. 414 (1990), the Supreme Court held that the government, despite the erroneous oral and written representations of a federal employee, was not equitably estopped from determining that a claimant who exceeded the statutory limit on earnings was ineligible for disability benefits. The Supreme Court concluded:

> Whether there are any extreme circumstances that might support estoppel in a case not involving payment from the Treasury is a matter we need not address. As for monetary claims, it is enough to say that this Court has never upheld an assertion of estoppel against the Government by a claimant seeking public funds. In this context, there can be no estoppel, for courts cannot estop the Constitution.

Id. at 434. *See also Columbus Reg'l Hosp. v. FEMA*, 708 F.3d 893, 899 (7th Cir. 2013) (agency employee could not commit agency to pay what was not permitted by statute and regulations); *Briscoe ex rel. Taylor v. Barnhart*, 425 F.3d 345, 356–57 (7th Cir. 2005) (explaining that "payment from U.S. Treasury must be authorized by statute").

Courts have applied the holding in *Richmond* to the Medicare context. In *Monongahela Valley Hospital v. Sullivan*, 945 F.2d 576 (3d Cir. 1991), the Third Circuit held that *Richmond* foreclosed a Medicare provider's estoppel claim against the Secretary for additional Medicare reimbursement. *Id.* at 588–89. Likewise, in *Downtown Medical Center/Comprehensive Health Care Clinic v. Bowen*, the Tenth Circuit declined to estop the Secretary and a private insurer, which processed Medicare claims on the Secretary's behalf, from denying the plaintiff's reimbursement claim. 944 F.2d 756, 771 (10th Cir. 1991). *See also Almy*, 679 F.3d at 312 ("It is the Secretary,

not the courts, who bears the responsibility for the disbursement of billions of dollars of public money under the Medicare system.").

The same reasoning applies to Plaintiffs' assertion of collateral estoppel. Plaintiffs seek to estop the Secretary from denying their claims payment from the Medicare Trust Fund. Of course, no appropriation of Congress entitles Plaintiffs to future payments from the Medicare Trust Fund. Because Plaintiffs seek to draw money from the Treasury on equitable grounds, the Court must deny their assertion of collateral estoppel.

B. The Elements of Collateral Estoppel are Not Met

Even if collateral estoppel could be invoked in this case, the elements have not been met. As an initial matter, ALJ Decision 1-8380637906, which Ms. Prosser submitted in support of her appeal to the Council, was decided eight days *after* ALJ Grow's decision, and can therefore have no preclusive effect. AR 4238–52. *See Adams v. City of Indianapolis*, 742 F.3d 720, 736 (7th Cir. 2014) (collateral estoppel "applies to prevent relitigation of issues resolved in an *earlier* suit") (emphasis added). Plaintiffs' argument that the later decision can be preclusive because it is "final" first, is without merit. Pls. Br. at 23. Appealing a decision, as Ms. Prosser did with ALJ Grow's decision, does not defeat the finality of the judgment. *Ross ex rel. Ross v. Bd. of Educ. Of Twp. High Sch. Dist. 211*, 486 F.3d 279, 284 (7th Cir. 2007).

As the party invoking collateral estoppel, it is plaintiffs' burden to show:

> (1) the issue sought to be precluded [was] the same as that involved in prior litigation,
> (2) the issue was actually litigated,
> (3) the determination of the issue [was] essential to the final judgment, and
> (4) the party against whom estoppel is invoked [was] fully represented in the prior action

In re Calvert, 913 F.3d 697, 701 (7th Cir. 2019)(citing *Matrix IV, Inc. v. Am. Nat'l Bank & Trust Co. of Chi*., 649 F.3d 539, 547 (7th Cir. 2011) (further quotations omitted). Plaintiffs have not carried their burden on the first, second, and fourth elements.

1. *The issues are not the same.*

First, because each ALJ decision concerns whether the TTFT treatment was covered by Medicare for a specific period of time, the issues in the appealed cases are not the same. Mr. Christenson is appealing (ALJ decision 1-8630709341) the denial of coverage for November 13, 2018, December 3, 2018, and January 3, 2019. AR 49–53. The other ALJ decisions do not cover this time period. AR 11–30. The same is true for Ms. Prosser. AR 4238–62. She appeals (ALJ decision 1-8390277469), which denied coverage for January 16, 2018, February 16, 2018, March 16, 2018, and April 16, 2018. AR 4310–15. Every favorable ALJ decision cited by Plaintiffs notes that the decision is limited to specific coverage dates. AR 11, 15, 24, 29, 4239, 4250, 4255, 4262. The time period of coverage is a key aspect of the ALJ decisions given that beneficiaries' medical conditions can change. The Seventh Circuit, in *Rucker v. Chater*, 92 F.3d 492, 495 (7th Cir. 1996), found that, in review of an application for Social Security disability benefits, an ALJ's determination that the claimant had the residual functional capacity (RFC) for sedentary work did preclude the ALJ in her second application (made while the district court reviewed the first denial) from determining she had the RFC for medium work. The court explained that the first ALJ's finding "was a binding determination with respect to Rucker's eligibility for disability benefits for that period. *It has no effect, however, on an application for disability benefits for a subsequent time period*." *Id*. (emphasis added). Because each ALJ decision in this case addresses a different time period, the issues were not the same and collateral estoppel cannot be invoked. *See, e.g.*, *In re Grand Jury Proceedings of Special Apr. 2002 Grand Jury*, 347 F.3d 197, 202 (7th Cir. 2003)

(finding collateral estoppel did not apply because appellant's state of mind during the prior grand jury proceedings where he refused to testify were not dispositive of his current state of mind in refusing to testify before a new grand jury even if he listed similar objections); *Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 435 F.3d 1356, 1361–62 (Fed. Cir. 2006) (declining to apply collateral estoppel where patent infringement involved two distinct time periods).

2. *The same issue was not actually litigated.*

As to the second element, again the differing time periods covered by each ALJ decision means that same issue was not actually litigated. The prior favorable decisions explicitly limited the time period of the coverage decisions, as do the Medicare regulations limiting the precedential effect of ALJs declining to follow an LCD, 42 C.F.R. § 405.1062(b). AR 11, 29–30, 4262. As such, plaintiffs cannot meet the second element. *See Donovan v. Fed. Clearing Die Casting Co*., 695 F.2d 1020, 1022 (7th Cir. 1982) (issue not actually litigated when issue left expressly undecided by decision); *Interoceanica v. Sound Pilots*, 107 F.3d 86, 91–92 (2d Cir. 1997) (finding issue not actually litigated or decided where prior decision explicitly stated it did not reach an issue); *California Communities Against Toxics v. EPA*, 928 F.3d 1041, 1052 (D.C. Cir. 2019) (finding issues not actually litigated where court stated it did "need not address" the issue).

3. *The Secretary was not fully represented in the prior actions.*

Finally, the fourth element is not met because the Secretary's opportunity to litigate is limited in Medicare coverage appeals. He cannot participate in the first two levels of the administrative appeals process. *See* 42 C.F.R. §§ 405.948, 405.968. *See Genesis Health Ventures, Inc. v. Sebelius*, 798 F. Supp. 2d 170, 182 (D.D.C. 2011) ("[I]f an intermediary finds coverage and pays a claim, there is never an administrative appeal, and the Secretary would have no knowledge of the intermediary's decision nor opportunity to review those actions."). The Secretary's

participation is also limited in ALJ appeals. When a beneficiary is unrepresented, the Secretary cannot be a party to the hearing. 42 C.F.R. § 405.1012(a). If the Secretary does not affirmatively elect to participate or become a party in ALJ proceedings, the proceedings move forward without the Secretary's involvement. 42 C.F.R. §§ 405.1010(a), 405.1012(b). Although the Secretary may participate or become a party in ALJ hearings involving beneficiaries represented by counsel, it is impracticable for the Secretary to litigate the over 400,000 Medicare claim appeals filed each year at the ALJ level. 42 C.F.R. §§ 405.1010(a), 405.1012; *see supra* n.2. *See* U.S. Government Accountability Office Report at 1, 12 (May 2016), https://www.gao.gov/assets/680/677034.pdf (last visited April 17, 2020); *also* 82 Fed. Reg. 4974, 4976 (Jan. 17, 2017) (noting that there were 650,000 pending ALJ appeals as of September 2016). If the Secretary does not become a party to an ALJ hearing, it cannot appeal a favorable ruling to the Council. 42 C.F.R. §§ 405.1012, 405.1102(a)(1), (d). In other words, the Secretary would need to litigate every ALJ hearing in order to have the right to appeal any decisions favorable to the beneficiary. Therefore, as the Secretary's opportunity to appeal was extremely limited, there was not a full and fair opportunity to litigate.

4. *The lack of incentive to litigate the ALJ decisions weighs against preclusion.*

Courts have also recognized an exception to applying preclusion even where all the elements for estoppel are met. Where there is an incentive against extensively litigating smaller matters (because cost outweighs the size of the issue), it is unfair to allow the decisions in those smaller matters to have large preclusive effects. Such is the case here, where the Secretary's involvement in the litigation of every claim would be an inefficient use of resources better put towards the Medicare program. Unreviewed and nonprecedential ALJ decisions should not be given preclusive effect, which would result in great cost to the Medicare Trust. *See Power Integrations v. Semiconductor Components Indus.*, 926 F.3d 1306, 1312, 1313 (Fed. Cir. 2019)

(holding that the exception of "a lack of opportunity or incentive to litigate the first action" prevented preclusion where there was a disparity in incentives to appeal an issue); *Rawls v. Daughters of Charity of St. Vincent De Paul*, 491 F.2d 141, 148 (5th Cir. 1974) (no preclusive effect given to habeas corpus hearing finding involuntary hospitalization was illegal in subsequent suit against hospital for false imprisonment because the hospital "had far less incentive to contest the unlawfulness of the plaintiff's detention than at present").

5. *Even if collateral estoppel applied, it would have no further force after the new LCD became effective on September 1, 2019*

Even if collateral estoppel applied here, it would have no force after the new LCD became effective on September 1, 2019. Collateral estoppel generally will not apply when "'controlling facts or legal principles have changed significantly since the [prior] judgment.'" *Karns v. Shanahan*, 879 F.3d 504, 514 (3d Cir. 2018) (alteration in original) (quoting *Montana*, 440 U.S. at 155. Here, there is no doubt that there was a significant change between the old LCD, which categorically denied coverage for TTFT treatment, and the new LCD, which allowed coverage of TTFT under certain circumstances. Accordingly, if Plaintiffs were to prevail on collateral estoppel, only the two ALJ decisions would be affected. Further preclusive or injunctive relief would not be warranted, because the new LCD has already been in place for over six months.

Similarly, the medical context of this case necessarily means that the controlling facts are constantly changing. Physicians do not prescribe treatment, no matter how potentially effective, indefinitely into the future. A treatment that may have been beneficial for a patient at one point in time could be ineffective or dangerous if continued (e.g., when a patient suffers serious side effects). In this case, there is no evidence that the facts supporting Plaintiffs' claims for coverage in 2018 are identical to the facts supporting their claims for coverage in 2020. Even if their medical history remained unchanged for two years, it would be pure speculation to assert that the facts

would remain unchanged for any claim they might file in the future. For example, if Plaintiffs filed claims for coverage, but the evidence showed that they were not actually using the device, Medicare should not be required to approve their claims. AR 127, 4266, 5393.

Because the controlling facts and law have changed, applying collateral estoppel would have zero benefit for Plaintiffs, who are not financially responsible for the claims on appeal. Meanwhile, a finding that favorable ALJ decisions have preclusive effect would have widespread, negative ramifications for the Medicare program, and millions of beneficiaries. Because collateral estoppel is fundamentally inconsistent with the Medicare Program, the court should grant summary judgment for the Secretary.

C. Plaintiffs Forfeited Any Argument that Substantial Evidence Does Not Support the ALJ Decisions

Finally, Plaintiffs have forfeited any argument that the ALJ decisions 1-8630709341 and 1-8390277469 are not supported by substantial evidence. The Seventh Circuit has held in similar administrative review cases that undeveloped arguments are waived, as are arguments not raised in the initial brief. *See Cent. States, Se. & Sw. Areas Pension Fund v. Midwest Motor Exp., Inc.*, 181 F.3d 799, 808 (7th Cir. 1999) (finding "arguments not developed in any meaningful way are waived."); *Jones v. Shalala*, 10 F.3d 522, 525 n.4 (7th Cir. 1993) (finding waiver where argument not developed in body of brief); *Darif v. Holder*, 739 F.3d 329, 336–37 (7th Cir. 2014) (finding argument waived where raised for the first time in reply brief); *Narducci v. Moore*, 572 F.3d 313, 324 (7th Cir. 2009) (same). Here, plaintiffs have argued only that the doctrine of collateral estoppel requires coverage of all plaintiffs' claims for TTFT. They made no argument that the ALJ decisions were not supported by substantial evidence. In the event plaintiffs attempt to raise the issue later, it should be deemed waived.

VI. CONCLUSION

For the foregoing reasons, the Secretary respectfully requests that the Court grant his cross-motion for summary judgment and deny Plaintiffs' motion for summary judgment.

Dated at Milwaukee, Wisconsin this 4th day of May, 2020.

Respectfully submitted,

MATTHEW D. KRUEGER
United States Attorney

By: /s/ Chris R. Larsen

CHRIS R. LARSEN
Assistant United States Attorney
Wisconsin State Bar Number: 1005336
Attorneys for Defendant
Office of the United States Attorney
Eastern District of Wisconsin
517 East Wisconsin Avenue, Room 530
Milwaukee, Wisconsin 53202
Telephone: (414) 297-1700
Fax: (414) 297-4394
Email: chris.larsen@usdoj.gov

Of Counsel:
ROBERT P. CHARROW
General Counsel

ALAN S. DORN
Chief Counsel, Region V

AMELIA WALLRICH
Assistant Regional Counsel
Office of General Counsel
United States Department of
Health and Human Services, Region V
233 North Michigan Avenue, Suite 700
Chicago, Illinois 60601

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

LYNN OXENBERG and RONALD LEWIS *Plaintiffs,* v. ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services, *Defendant*.	Civil Action No. 20-738-CMR

ORDER

AND NOW, this _____ day of _____, 2020, upon consideration of the Motions for Summary Judgment filed by each party and any responses thereto, it is ORDERED that:

(1) Defendant's motion is GRANTED;

(2) Plaintiffs' motion is DENIED;

(3) Pursuant to 42 U.S.C. § 405(g) (made applicable by 42 U.S.C. § 1395ii), judgments are entered affirming the following decisions of Defendant, Alex M. Azar, II, Secretary of the U.S. Department of Health and Human Services:

a. the unfavorable decision in Office of Medicare Hearings and Appeals ("OMHA") Appeal Number 1-8411344383 against Plaintiff Ronald Lewis, dated May 30, 2019; and

b. the unfavorable decision in OMHA Appeal Number 1-8393258352 against Plaintiff Lynn Oxenberg, dated September 5, 2019; and

(4) The Clerk of the Court shall enter the foregoing judgments and mark this case CLOSED.

BY THE COURT:

HONORABLE CYNTHIA M. RUFE
Judge, United States District Court

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

LYNN OXENBERG and RONALD LEWIS *Plaintiffs,* v. ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services, *Defendant*.	Civil Action No. 20-738-CMR

DEFENDANT'S CROSS-MOTION FOR SUMMARY JUDGMENT

Defendant Alex M. Azar, II, Secretary of the U.S. Department of Health and Human Services (the "Secretary"), moves this Court pursuant to 42 U.S.C. § 405(g) (made applicable by 42 U.S.C. § 1395ii), Fed. R. Civ. P. 56(a), and the Court's April 3, 2020 Order [Dkt. 14] to enter summary judgment for the Secretary. Additionally, the Court should deny the Motion for Summary Judgment filed by Plaintiffs Lynn Oxenberg and Ronald Lewis [Dkt. 12] on March 30, 2020.

As grounds for this cross-motion, the Court is referred to the following materials filed in support of the motion:

a. the Secretary's brief in support of this motion;

b. the Secretary's answer to the complaint; and

c. the certified Administrative Record.

Respectfully submitted,

WILLIAM M. McSWAIN
United States Attorney

/s/ Susan R. Becker
for Gregory B. David
GREGORY B. DAVID
Assistant United States Attorney
Chief, Civil Division

/s/ Eric S. Wolfish
ERIC S. WOLFISH
Special Assistant United States Attorney/
Assistant Regional Counsel, HHS
Eric.Wolfish@hhs.gov

/s/ Matthew E. K. Howatt
MATTHEW E. K. HOWATT
Assistant United States Attorney
United States Attorney's Office
615 Chestnut Street, Suite 1250
Philadelphia, PA 19106
Tel: 215-861-8335
Fax: 215-861-8618
Matthew.Howatt@usdoj.gov

Dated: April 20, 2020

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

LYNN OXENBERG and RONALD LEWIS *Plaintiffs,* v. ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services, *Defendant*.	Civil Action No. 20-738-CMR

DEFENDANT'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF HIS CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

I. INTRODUCTION

Plaintiffs Lynn Oxenberg and Ronald Lewis are suffering from a terrible and deadly form of brain cancer, glioblastoma multiforme ("GBM"). This case involves judicial review of the denial of two Medicare claims, one for each Plaintiff, for certain months of tumor treatment field therapy ("TTFT") to treat GBM. [1] Plaintiffs raise a single issue on appeal: whether the Secretary of the Department of Health and Human Services (the "Secretary") is *forever* collaterally estopped from denying Plaintiffs' TTFT claims because an administrative law judge ("ALJ") allowed coverage for certain months of TTFT claims. But Plaintiffs are simply wrong on the law: there is no collateral estoppel here.

The United States cannot be estopped on the same terms as a private litigant, and the Supreme Court has never upheld an assertion of offensive collateral estoppel against the United States. *Heckler v. Community Health Servs. Of Crawford Co., Inc.*, 467 U.S. 51, 60 (1984); *United States v. Mendoza*, 464 U.S. 154, 159-60 (1984). Although Plaintiffs assert offensive collateral estoppel against the Secretary, they admit that Medicare ALJ decisions have "no precedential effect." Certified Administrative Record ("CAR") at 55. Plaintiffs' admission is consistent with the applicable Medicare statute and regulations, which prohibit ALJ decisions from having any preclusive effect in future cases. *See, e.g.*, 42 U.S.C. § 1395ff(d)(2)(B); 42 C.F.R. § 405.1062(b).

Indeed, the case that Plaintiffs principally rely upon in support of collateral estoppel held that preclusion cannot apply when there is a statutory purpose to the contrary, as there is here. *See Astoria Fed. Sav. & Loan Ass'n v. Solimino*, 501 U.S. 104, 108 (1991). Giving preclusive

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[1] Plaintiffs are not financially responsible for paying for the TTFT claims at issue if Medicare does not cover it. *See infra* § II.F.

effect to ALJ decisions would also interfere with the Secretary's discretion to permit case-by-case adjudication of Medicare claims. *See Heckler v. Ringer*, 466 U.S. 602, 617 (1984). While Plaintiffs fail to cite any cases on point, the Fourth, Fifth, Seventh, Ninth, and D.C. Circuits have followed the Supreme Court's reasoning and rejected similar attempts to bind federal agencies to non-precedential decisions in administrative appeals. *See infra* § IV.B.2.

The Court should reject Plaintiffs' assertion of collateral estoppel for five additional reasons. First, the Medicare statute's presentment and channeling requirements bar Plaintiffs' attempt to circumvent the administrative appeals process by seeking a judicial determination that the Secretary must cover future claims. 42 U.S.C. § 405(g), (h); *Ringer*, 466 U.S. at 620-21; *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000); *Porzecanski v. Azar*, 943 F.3d 472, 483 (D.C. Cir. 2019). Second, the Appropriations Clause of the Constitution prohibits estoppel claims for the payment of money from the federal government. Art. I, § 9, cl. 7; *Office of Personnel Management v. Richmond*, 496 U.S. 414, 424-25 (1990). Third, the elements of collateral estoppel are not present here. Notably, Plaintiffs' claim appeals involved different issues. The ALJs who approved Plaintiffs' claims expressly limited their holdings to certain months of TTFT treatment and *never* decided whether future claims for treatment should be allowed. Plaintiff Lewis cannot assert collateral estoppel because the "unfavorable" decision at issue in this case pre-dates his only "favorable" decision. *See infra* § IV.A. In addition, the Secretary did not have a full and fair opportunity to litigate Plaintiffs' appeals.

Fourth, fairness is an essential element for the application of offensive collateral estoppel. It is impracticable for the Secretary to appear as a party in the *over 400,000* Medicare claim

appeals that are filed each year at the ALJ level.[2] It would therefore be unfair to conclude that the Secretary has opened the door to collateral estoppel. A finding that favorable ALJ decisions collaterally estop the Secretary would also have widespread, negative ramifications for the Secretary and Medicare beneficiaries. The Secretary would be forced to devote Medicare resources to actively litigate hundreds of thousands of ALJ appeals to avoid the risk of collateral estoppel, thereby taking resources away from tens of millions Medicare beneficiaries.

Finally, collateral estoppel does not apply when the controlling legal principles or facts have significantly changed. *Montana v. United States*, 440 U.S. 147, 155 (1979). The Local Coverage Determination ("LCD") in effect at the time of the unfavorable decisions categorically denied Medicare coverage for TTFT. A new LCD that became effective on September 1, 2019 allows TTFT coverage in certain circumstances (the "2019 LCD"). Because the controlling legal principle underlying the unfavorable decision has significantly changed, if collateral estoppel were legally supportable – which it is not – it could not be applied after the issuance of the 2019 LCD.

Because the application of collateral estoppel to ALJ decisions is contrary to the Constitution, the Medicare statute and regulations, Supreme Court precedent, and numerous circuit-level decisions, summary judgment should be granted in the Secretary's favor and Plaintiffs' motion for summary judgment should be denied.[3]

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[2] *See* U.S. Government Accountability Office Report at 1, 12 (May 2016), https://www.gao.gov/assets/680/677034.pdf (last visited April 17, 2020); *also* 82 Fed. Reg. 4974, 4976 (Jan. 17, 2017) (noting that there were 650,000 pending ALJ appeals as of September 2016).

[3] Plaintiffs' summary judgment motion abandons any arguments other than collateral estoppel. *See* Plaintiffs' summary judgment brief [Dkt. 12] (Pl. Br.) at 1-3, 10 (raising only collateral estoppel). Because Plaintiffs' have abandoned any other grounds to challenge the ALJ decisions at issue, the Secretary does not address them.

II. STATUTORY AND REGULATORY BACKGROUND

A. "Reasonable and Necessary" Medicare Expenses

Medicare is a federal health insurance program for people who are elderly and/or have disabilities. *See* 42 U.S.C. § 1395. For a medical service to be covered by Medicare, it must fit within a benefit category established by the Medicare statute. *Id*.

This case concerns Medicare Part B, which extends coverage to certain types of durable medical equipment ("DME") for qualified recipients. 42 U.S.C. §§ 1395k(a), 1395x(s)(6). The various benefit categories available under Medicare Part B are set forth in 42 C.F.R. part 410. Almost all Medicare coverage determinations, including those in this case, are subject to 42 U.S.C. § 1395y(a)(1)(A), which excludes certain items from coverage. Under this section, "no payment may be made under . . . part B of this subchapter for any expenses incurred for items or services[] which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member . . . ." 42 U.S.C. § 1395y(a)(1)(A). Unless there is an exception, this bar applies "[n]othwithstanding any other provision" of the Medicare statute. 42 U.S.C. § 1395y(a)(1)(A). The Centers for Medicare & Medicaid Services ("CMS"), which administers the Medicare program for the Secretary, has historically interpreted "reasonable and necessary" to mean that an item or service must be safe and effective, medically necessary and appropriate, and not experimental in order to qualify for reimbursement. *See* Medicare Program Integrity Manual ("MPIM") § 13.5.4.[4]

[4] The MPIM is available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf. The MPIM "is a compilation of guidelines which CMS issues to instruct Medicare contractors on how to conduct medical review of Medicare claims submitted by Medicare providers and suppliers for payment." *Erringer v. Thompson*, 371 F.3d 625, 628 (9th Cir. 2004).

To administer the "reasonable and necessary" standard, the Secretary employs a range of tools, from formal regulations to informal manuals. In choosing among these options, the Secretary is not required to promulgate regulations or policies that, "either by default rule or by specification, address every conceivable question" that may arise. *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 96 (1995). The Secretary may articulate "reasonable and necessary" standards through formal regulations that have the force and effect of law throughout the administrative process. *See* 42 U.S.C. §§ 1395hh; 1395ff(a)(1). The Secretary may also issue National Coverage Determinations ("NCDs") "with respect to whether or not a particular item or service is covered nationally." 42 U.S.C. § 1395ff(f)(1)(B); *see also* 42 C.F.R. §§ 400.202, 405.1060.

B. Enforcement of the "Reasonable and Necessary" Standard Through Local Coverage Determinations ("LCDs")

The Secretary has delegated to CMS broad authority to determine whether Medicare covers particular medical services.[5] CMS, in turn, contracts with Medicare Administrative Contractors ("MACs"), such as Noridian Healthcare Solutions in this case, to administer certain day-to-day functions of the Medicare program. 42 U.S.C. § 1395kk-1. Consistent with controlling regulations and NCDs, a MAC makes coverage determinations, issues payments, and develops LCDs for the geographic area it serves, *see* 42 U.S.C. § 1395ff(f)(2)(B), in accordance with the reasonable and necessary provisions in 42 U.S.C. § 1395y(a)(1). *See* 42 U.S.C. §§ 1395kk-1(a)(4), 1395ff(f)(2)(B). An LCD is binding only on the contractor that issued it, and

[5] *See* 42 U.S.C. §§ 1395y(a), 1395ff(a), (f).

only at the initial stages of the Medicare claim review process, as opposed to later stages if a claimant should appeal a determination by a MAC. 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II).

In developing LCDs, such as the one at issue in this case, MACs follow guidance contained in the MPIM. The MPIM requires MACs to publish LCDs that specify when "an item or service is considered to be reasonable and necessary." MPIM § 13.5.4. MACs develop LCDs by considering medical literature, the advice of local medical societies and medical consultants, public comments, and comments from the provider community. MPIM §§ 13.2.3, 13.5.2.1, 13.5.3, 13.5.5; 66 Fed. Reg. 58,788, 58,788 (Nov. 23, 2001). MACs also follow detailed procedures for issuing new or substantively revised LCDs, including engaging in a comment-and-notice period, soliciting feedback and recommendations from the medical community, and presenting the policy in meetings of stakeholders. MPIM § 13.2.1.

C. The Process of Promulgating LCDs

New LCDs require both a notice period and a comment period. MPIM § 13.2.4.2. The MAC first issues a draft LCD and provides the public a minimum of 45 days to comment on it. LCDs are principally based upon "available evidence of general acceptance by the medical community, such as published original research in peer-reviewed medical journals, systematic reviews and meta-analyses, evidence-based consensus statements and clinical guidelines." MPIM § 13.5.3. After considering all of the comments and revising the LCD as needed, the contractor publishes the final LCD, providing at least a 45-day notice period before the LCD goes into effect. *Id*. at § 13.2.6.

D. The LCD for TTFT Devices

In April 2011, the United States Food and Drug Administration approved the marketing of the NovoTTF-100A device (later rebranded Optune) manufactured and supplied to

beneficiaries by Novocure, for the treatment of recurrent GBM. CAR at 141.[6] Following an open meeting and solicitation of public comments, in August 2014, the DME MACs issued the original LCD for TTFT. *Id.* "The DME MACs determined that, based on the strength and quality of the evidence available at that time, TTFT was not reasonable and necessary for the treatment of GBM." *Id.* The LCD in effect at the relevant time, *i.e.*, during the dates of service for the claims on appeal, remained substantively unchanged and stated that "Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary." CAR at 13.

In 2018, Novocure requested that the DME MACs approve Medicare payment of TTFT for newly diagnosed GBM. CAR at 141. Effective September 1, 2019, the LCD was revised to permit coverage for newly diagnosed GBM and continued coverage for newly diagnosed GBM beyond the first three months of therapy in certain circumstances. CAR at 136-37. Novocure was "extremely pleased" with the 2019 LCD and notes that its coverage criteria "is generally similar to Optune's commercial coverage criteria for newly diagnosed GBM."[7]

E. Claims and Administrative Appeals

In order for a beneficiary to challenge a denial of a claim under the Medicare statute, he or she must submit a claim for payment to the Medicare contractor, and if the claim is denied, the beneficiary must generally exhaust the following four levels of administrative review before filing suit in district court. *See generally* 42 U.S.C. § 1395u(a); 42 C.F.R. § 405.904. First, the

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[6] Plaintiff Oxenberg cited the 2019 LCD in her appeal (CAR at 108, 132-53), which is also available at: https://med.noridianmedicare.com/documents/2230703/7218263/Tumor+Treatment+Field+Therapy+%28TTFT%29%20LCD+and+PA/8f195ce1-c8e1-4c92-8578-f2b8996e4507 (last visited April17, 2020).

[7] *See* Medicare Releases Final Local Coverage Determination Providing Coverage of Optune® for Newly Diagnosed Glioblastoma, https://www.novocure.com/medicare-releases-final-local-coverage-determination-providing-coverage-of-optune-for-newly-diagnosed-glioblastoma/ (last visited April 17, 2020).

beneficiary may seek a redetermination from the Medicare contractor, which must be performed by a person who did not make the initial decision. 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. §§ 405.920, 405.940. At the second level, a beneficiary may seek reconsideration by a qualified independent contractor ("QIC") whose panel members must have "sufficient medical, legal, and other expertise, including knowledge of the Medicare program." 42 U.S.C. § 1395ff(b)(1)(A), 1395ff(c); 42 C.F.R. §§ 405.960, 405.968(c)(1). An LCD is not binding at this and at higher levels of appeal. 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II); 42 C.F.R. § 405.968(b). At the third level, a beneficiary can request a hearing before an ALJ, who issues a decision based on the evidence presented at the hearing or otherwise admitted into the administrative record by the ALJ. 42 U.S.C. § 1395ff(b)(1)(A), 1395ff(d); 42 C.F.R. §§ 405.1000-02, 405.1042, 405.1046.

The administrative process ends in a review of the ALJ's decision by the Medicare Appeals Council (the "Council"), a division of the Departmental Appeals Board of the Department of Health and Human Services. 42 U.S.C. § 1395ff(b)(1)(A), (d)(2); 42 C.F.R. §§ 405.1100, 405.1122. The Council's decision (or the ALJ decision, if not reviewed by the Council) represents the final decision of the Secretary for purposes of administrative exhaustion. 42 U.S.C. § 1395ff(b)(1)(A), (d)(2)(A); 42 C.F.R. §§ 405.1048, 405.1130, 405.1136. If the Council does not render a decision within a specified time frame, a beneficiary may request elevation to district court. 42 C.F.R. § 405.1132.

The claimant is entitled to judicial review of the Secretary's decision in the district court "as is provided in [42 U.S.C.] 405(g)." 42 U.S.C. § 1395ff(b)(1)(A). In such review, the Secretary's findings of fact "if supported by substantial evidence, shall be conclusive." 42 U.S.C. § 405(g).

F. Advanced Beneficiary Notices

If Medicare coverage is denied, Medicare will nevertheless pay the claim if neither the supplier nor the beneficiary knew or could reasonably have been expected to know that the item would not be covered. 42 U.S.C. § 1395pp; 42 C.F.R. § 411.400(a). The supplier can shift the risk of non-coverage to the beneficiary by providing him with advance written notice (called an "Advance Beneficiary Notice") of the specific reason why the item probably will not be covered. 42 C.F.R. § 411.404(b). As the ALJs found, because Novocure did not require Plaintiffs to sign an Advance Beneficiary Notice, no matter the outcome of this case, they will not be financially responsible for the TTFT claims at issue. *See* CAR at 109, 839.

G. Plaintiffs' Claims and Administrative Exhaustion

This case arises from the denial of Plaintiffs' claims for Medicare coverage of certain months of treatment with the Optune system for their GBM. Compl. [Dkt. 1] ¶¶ 21, 27. Plaintiffs have fully exhausted their administrative remedies, because the ALJ decisions denying their claims became final when the Council did not timely respond to their notices of escalation. *Id.* ¶ 5. Plaintiffs filed the instant action instead of seeking a hearing before the Council. CAR at 1-2, 726-27.

III. STANDARD OF REVIEW

Even though cross-motions for summary judgment are before the Court, the standard articulated in Federal Rule of Civil Procedure 56 is inapplicable because the Court has a more limited role in reviewing the administrative record. *Uddin v. Mayorkas*, 862 F. Supp. 2d 391, 399 (E.D. Pa. 2012); *Wilhelmus v. Geren*, 796 F. Supp. 2d 157, 160 (D.D.C. 2011). Instead, summary judgment is the "mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard

of review." *La. Forestry Ass'n, Inc. v. Solis*, 889 F. Supp. 2d 711, 720 (E.D. Pa. 2012) (quoting *Sierra Club v. Mainella*, 459 F. Supp. 2d 76, 90 (D.D.C. 2006)), *aff'd sub nom. La. Forestry Ass'n Inc. v. Sec'y U.S. Dep't of Labor*, 745 F.3d 653 (3d Cir. 2014).

For appeals arising under section 405(g), a court must uphold an ALJ's findings if they are supported by substantial evidence. *See McGinnis v. Social Security Admin.*, 2020 WL 1623703, at *2 (3d Cir. Apr. 2, 2020); *Rutherford v. Barnhart*, 399 F.3d 546, 552 (3d Cir. 2005). Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Rutherford*, 399 F.3d at 552 (citation omitted). It is "more than a mere scintilla but may be somewhat less than a preponderance of the evidence." *Id*. (citation omitted).

IV. ARGUMENT

A. Plaintiffs' Irrelevant Evidence and Argument Outside of the Administrative Record Should be Excluded

As a threshold matter, the Court's decision in this claim appeal must be based *only* upon the certified administrative record. Plaintiffs concede that judicial review in this case is authorized by 42 U.S.C. § 405(g) (made applicable to the Secretary by 42 U.S.C. 1395ii), *see* Compl. at ¶ 5, Pl. Br. at 10, which says in the relevant part:

> As part of the [Secretary]'s answer the [Secretary] shall file a certified copy of the transcript of the record including the evidence upon which the finding and decision complained of are based. The court shall have power to enter, *upon the pleadings and transcript of the record*, a judgment affirming, modifying, or reversing the decision of the [Secretary], with or without remanding the cause for a rehearing.

(emphasis added). Accordingly, Plaintiffs' proffered evidence and argument that is outside of the administrative record is not properly within the scope of this appeal and should be excluded from the Court's consideration of this case. *See SEC v. Chenery Corp.*, 318 U.S. 80, 87 (1943) ("[t]he grounds upon which an administrative order must be judged are those upon which the

record discloses that its action was based."); *Fargnoli v. Massanari*, 247 F.3d 34, 44 n.7 (3d Cir. 2001) (applying *Chenery* in cases arising under section 405(g)); *Jones v. Soc. Sec. Admin.*, 2018 WL 5817351, at *4 (D.D.C. Nov. 7, 2018) ("[T]he Court's review is confined to the administrative record that was before the ALJ at the time of the decision[.]"); *Debaise v. Astrue*, 2010 WL 597488, at *14 (W.D. Pa. Feb. 16, 2010) ("[T]he Court cannot undertake a de novo review of the Commissioner's decision or consider evidence outside the record.").

Plaintiff Lewis' unfavorable decision on appeal is dated May 30, 2019. The court should exclude Lewis' *subsequent* favorable decision, dated October 24, 2019. *See* Ex. F to Pl. Br. Because the favorable decision was issued months *after* the unfavorable decision, it was not part of the administrative record. *See* CAR at 833-844 (5/30/19 ALJ Decision), 849 (ALJ Exhibit List). Collateral estoppel cannot apply as to Plaintiff Lewis, because the unfavorable decision on appeal *predates* his favorable ALJ decision. *See* Pl. Br. at 2 (asserting that an earlier-decided case may have preclusive effect). Therefore, because Plaintiff Lewis has appealed only on collateral estoppel grounds, the Court should grant summary judgment in the Secretary's favor.[8]

Likewise, the unfavorable decision Plaintiff Oxenberg presents on appeal is dated September 5, 2019. Accordingly, the Court should exclude her simultaneous or subsequent favorable decisions, dated September 5, 2019 and October 24, 2019. *See* Exs. B, C to Pl. Br. Plaintiff Oxenberg did not identify these decisions in the Complaint; the decisions were not in the record before the ALJ who rendered the decision; and they are irrelevant to Plaintiff Oxenberg's collateral estoppel argument. *See* CAR at 103-114 (9/5/19 ALJ Decision), 115 (ALJ Exhibit List).

[8] Indeed, the timing of the ALJ decisions alone disposes of Plaintiff Lewis' claim. Unless specifically noted, the following arguments apply to both Plaintiffs' claims. However, the Court need not reach them as to Plaintiff Lewis.

In addition, Plaintiffs' brief contains a number of gratuitous assertions for which they give no evidentiary support and, in any event, are far outside the administrative record and the scope of the issues on appeal in this case. Pl. Br. at 6 (personal facts regarding Plaintiff Oxenberg), 9 (personal facts regarding Plaintiff Lewis), 13-14 ("Response to the Secretary's Comments Regarding Coverage and Financial Responsibility"). In particular, Plaintiffs have not introduced any evidence concerning the status of their recent TTFT claims. Novocure is not a party to this federal court appeal and there is no evidence Novocure has required Plaintiffs to sign Advance Beneficiary Notices in order to continue receiving treatment, or is even considering that possibility. Each of these issues would require discovery, which the parties agree is unnecessary in an administrative record review case such as this. *See* Report of Rule 26(f) Meeting [Dkt. No. 11] at 2 ("As this case can be decided on administrative records, no discovery is necessary."). Regardless, Plaintiffs' arguments in this regard are irrelevant and the Court should disregard them.[9]

B. The Common Law Doctrine of Collateral Estoppel is Inapplicable in Medicare Claim Appeals

1. ALJ Decisions expressly do not bind the Secretary in future cases.

Although Plaintiffs primarily base their collateral estoppel argument on a passage from the U.S. Supreme Court decision in *Astoria*, Pl. Br. at 2-3,[10] they tellingly omit the very next

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[9] To the extent that issues about Plaintiffs' current health status arose during status conferences, they were in response to the Court's concerns about how that should affect scheduling.

[10] In *Astoria*, the Court considered whether claimants alleging age discrimination under federal law are "collaterally estopped to re-litigate in federal court the judicially unreviewed findings of a state administrative agency made with respect to an age-discrimination claim." 501 U.S. at 106. The Court held that the state court's findings had no preclusive effect on federal proceedings. *Id.* Because the federal government was not a party, and the Court found the *absence* of estoppel, Plaintiffs' cited language is mere dicta.

paragraph, which explains that preclusion cannot apply when there is a statutory purpose to the contrary: "Courts do not, of course, have free rein to impose rules of preclusion, as a matter of policy, when the interpretation of a statute is at hand[,] ... [and] the question is not whether administrative estoppel is wise but whether it is intended by the legislature." 501 U.S. at 108. The Third Circuit has also held that collateral estoppel may not be applied if it would "frustrate congressional intent or impede the effective functioning of the agency." *Duvall v. Atty. Gen. of U.S.*, 436 F.3d 382, 387-88 (3d Cir. 2006) (citing *Astoria* at 108-11). Here, the Medicare statute and regulations clearly bar the application of collateral estoppel to ALJ decisions.[11]

The Medicare regulations sharply distinguish between a narrow category of precedential decisions that are binding on future administrative appeals and the remainder of non-precedential decisions that are not binding. Only Council-level decisions have the potential to become precedential, which occurs only if they are so designated by the Chair of the Departmental Appeals Board. 42 C.F.R. § 401.109. Council decisions designated as precedential must be made available to the public, with personally identifiable information removed, and notice of precedential decisions must be published in the Federal Register. 42 C.F.R. § 401.109(b). That decision is then given "precedential effect" and is binding on "all HHS components that adjudicate matters under the jurisdiction of CMS." *Id.* § 401.109(c).[12] The term "precedential effect" means that the Council's:

> (1) Legal analysis and interpretation of a Medicare authority or provision is binding and must be followed in future determinations and appeals in which the same authority or provision applies and is still in effect; and

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[11] Plaintiffs' reliance on *B & B Hardware, Inc. v. Hargis Indus., Inc.*, is also misplaced, Pl. Br. at 3, because the case involved private parties, and the Court did not consider whether the federal government may be bound by administrative decisions. 575 U.S. 138 (2015).

[12] HHS is the United States Department of Health and Human Services.

> (2) Factual findings are binding and must be applied to future determinations and appeals involving the same parties if the relevant facts are the same and evidence is presented that the underlying factual circumstances have not changed since the issuance of the precedential final decision.

Id. § 401.109(d). Accordingly, the term "precedential effect" is synonymous with a decision having binding or preclusive effect.

It is undisputed that no Council decision, much less one designated as precedential, has favorably decided Plaintiffs' claims. Accordingly, nothing in the Medicare statute or regulations binds the Secretary to approve Plaintiff's TTFT treatment. *See Almy v. Sebelius*, 679 F.3d 297, 310 (4th Cir. 2012) (finding that the Secretary could not have departed from prior precedent because there were no Council-level decisions finding that the device at issue was "reasonable and necessary" or "safe and effective").

Instead, Plaintiffs' collateral estoppel argument relies upon a favorable ALJ decision that departed from the LCD and approved TTFT treatment.[13] However, an ALJ's decision to depart from an LCD "applies only to the specific claim being considered and does not have precedential effect." 42 C.F.R. § 405.1062(b) (emphasis added); 70 Fed. Reg. 11420, 11458 (Mar. 8, 2005) ("[T]he ALJ or [Council] may decline to follow a policy in a particular case, but must explain the reason why the policy was not followed. These decisions apply only for purposes of the appeal in question, and do not have precedential effect."). The regulations re-affirm that only "[p]recedential decisions designated by the Chair of the Departmental Appeals Board in accordance with § 401.109 of this chapter, are binding . . . ." 42 C.F.R. § 405.1063(c). "Nowhere does any policy or regulation suggest that the [Council] owes any deference at all to—

[13] ALJs are not bound by LCDs, but are required to afford them "substantial deference." 42 C.F.R. § 405.1062(a). ALJs are not authorized to "set aside or review the validity of an . . . LCD for purposes of a claim appeal." *Id.* § 405.1062(c).

much less is bound by—decisions of lower reviewing bodies addressing different disputes between different parties merely because they pertain to the same device." *Almy*, 679 F.3d at 310. Indeed, ALJ decisions are not even binding upon lower levels of administrative review, such as the QIC second level of review. *See* 42 C.F.R. § 405.968(b) (omitting ALJ decisions among the rulings that bind the QIC). Plaintiffs also agree that ALJ decisions are not precedential. CAR at 55 ("An ALJ's decision to decline to follow an LCD in a particular case has no precedential effect . . . .").

Giving preclusive effect to ALJ decisions is also contrary to the Medicare statute, which provides that the Council must "review the case de novo." 42 U.S.C. § 1395ff(d)(2)(B) (emphasis added); *see Porzecanski*, 943 F.3d at 477 ("Because the review generally binds only the parties unless specifically designated as precedential, a favorable determination in one proceeding does not ensure that future claims will be approved.") (citing 42 C.F.R. §§ 401.109, 405.1130, 405.1048). If a favorable ALJ ruling collaterally estopped the Council from denying a beneficiary's claim for the same treatment, the Council could not perform a de novo review; instead, the Council would be bound to accept the ALJ's conclusions. *Almy*, 679 F.3d at 303 (concluding that the Council's obligation to undertake "de novo" review was "incompatible with [plaintiff's] proffered notion that the [Council] is somehow obligated to defer to the outcomes of prior decisions below").

Because the Medicare regulations specifically designate ALJ decisions as non-binding and non-precedential, and the application of collateral estoppel is contrary to the Medicare statute, collateral estoppel cannot apply here. *See Astoria* at 111–12 (rejecting application of collateral estoppel to a federal statute because applying the principle would render a section of that statute superfluous).

2. Collateral estoppel interferes with the discretion and deference afforded to the Secretary to implement the Medicare Statute.

If ALJ decisions were deemed binding, they would also interfere with the deference and discretion afforded to the Secretary to implement the Medicare statute's "reasonable and necessary" standard for coverage of items and services furnished to program beneficiaries. "[T]he choice made between proceeding by general rule or by individual, *ad hoc* litigation is one that lies primarily in the informed discretion of the administrative agency." *SEC v. Chenery Corp.*, 332 U.S. 194, 203 (1947). The Medicare statute and regulations preserve "this discretion for the Secretary, leaving it to her judgment whether to proceed by implementing an NCD, by allowing regional contractors to adopt an LCD, or by deciding individual cases through the adjudicative process." *Almy*, 679 F.3d at 303. The Supreme Court has foreclosed arguments that interfere with this discretion, holding that "[t]he Secretary's decision as to whether a particular medical service is 'reasonable and necessary' and the means by which she implements her decision, whether by promulgating a generally applicable rule or by allowing individual adjudication, are clearly discretionary decisions." *Ringer*, 466 U.S. at 617; *see also Guernsey Mem'l Hosp.*, 514 U.S. at 97 ("The Secretary's mode of determining benefits by both rulemaking and adjudication is, in our view, a proper exercise of her statutory mandate.").

As noted above, the Medicare regulations designate ALJ decisions as non-binding and non-precedential, which allows individual adjudication over Part B claims. Generally speaking, this inures to the benefit of Medicare beneficiaries, who, even after repeated denials of similar claims, have the right to de novo review of any subsequent claims. The application of collateral estoppel, therefore, is fundamentally inconsistent with individual adjudication of Part B claims. In Plaintiffs' view, once a claim for benefits is approved, the Secretary would be estopped from ever denying a claim for the same treatment. Pl. Br. at 10. Individual adjudication would be

impossible, because the earliest-in-time ALJ ruling would forever bind the Secretary. Accordingly, it is within the Secretary's discretion *not* to be bound by ALJ rulings. *See generally Ringer*, 466 U.S. at 607-08 (distinguishing between ALJ and Council-level decisions that "applied only to the claimants involved in that case and [were] not to be cited as precedent in future cases" and a subsequent formal administrative ruling by the Secretary that bound ALJs and the Council).

Here, the Secretary's decision that ALJ decisions are non-binding and non-precedential is expressed in the plain, unambiguous language of the applicable law and regulations. *See Avalon Place Trinity*, DAB No. 2819, at 13 (2017) ("An unappealed ALJ decision [does not set] a precedent binding on ALJs or the Board. When the *Board* has not reviewed the ALJ decision, the *Board* has not issued a decision in that case. Regardless of whether an ALJ decision was appealed to the Board, an ALJ decision is not precedential and does not bind the Board, and is relevant in later cases only to the extent its reasoning is on point and persuasive.") (italics in original), *aff'd*, *Avalon Place Trinity v. HHS*, 761 F. App'x 407 (5th Cir. Mar. 4, 2019). Again, it is undisputed that ALJ decisions "have no precedential effect." CAR at 55. Because giving preclusive effect to ALJ rulings would contravene the Medicare regulations, the Court should decline to apply collateral estoppel here.

While Plaintiffs fails to cite any cases on point,[14] the Fourth, Fifth, Seventh, Ninth, and D.C. Circuits have each rejected similar attempts to bind federal agencies to non-precedential

[14] Plaintiffs' reliance on the unpublished decision in *Brewster v. Barnhart*, 145 F. App'x 542 (6th Cir. 2005) is misplaced. Pl. Br. at 3. The court found that, under circumstances unique to Social Security disability appeals, an applicant (not the government) was bound by an ALJ's earlier finding concerning the exertion level of the applicant's past work. *Id.* at 546-48. Plaintiffs' additional citation, Pl. Br. at 3, to a case concerning the unique circumstances of immigration appeals is similarly unhelpful. *Islam v. U.S. D.H.S.*, 136 F. Supp. 3d 1088 (N.D.

decisions in lower-level administrative appeals. In *Almy*, plaintiff asserted that Council decisions denying coverage for a medical device created a policy of denying treatment for that device. 679 F.3d at 299. The Fourth Circuit disagreed, noting that "[t]he Secretary's own regulations make clear that any policy implications in an adjudication do not have precedential effect. . . . The purported 'policy' in this case is nothing more than the accretion of individual decisions finding that the [device] does not meet the statutory requirements for coverage." *Id.* at 303 (citing 42 C.F.R. § 405.1062). The Fourth Circuit noted that Congress gave the Secretary discretion to "decide how to deal with hundreds of millions of Part B claims for coverage of thousands of devices every year." *Id.* at 304. Likewise, this Court should reject Plaintiffs' attempt to elevate non-precedential ALJ opinions into binding coverage rules, which would "stultify the administrative process." *Id.* (quoting *Chenery*, 332 U.S. at 202).

The Fourth Circuit noted that other circuits have concluded that "[t]here is no authority for the proposition that a lower component of a government agency may bind the decision making of the highest level . . . [E]ven if these cases were found to evince internal inconsistency at a subordinate level, the [agency] itself would not be acting inconsistently." *Id.* at 310 (quoting *Community Care Found. v. Thompson*, 318 F.3d 219, 227 (D.C. Cir. 2003)). Along the same lines, the D.C. Circuit has emphasized its "well-established view that an agency is not bound by the actions of its staff if the agency has not endorsed those actions." *Comcast Corp. v. FCC*, 526 F.3d 763, 769 (D.C. Cir. 2008) (citing cases). Instead, "a definitive and binding statement on behalf of the agency must come from a source with the authority to bind the agency." *Devon*

Cal. 2015). Among other things, unlike the Medicare statute and regulations' prohibition on collateral estoppel here, the *Islam* court determined that the Immigration and Nationality Act permitted collateral estoppel of issues decided by an Immigration Judge in granting asylum. *Id.* at 1093-94. Additionally, unlike here, the other elements of collateral estoppel were actually met in *Islam*. *Id.* at 1091-93.

Energy Corp. v. Kempthorne, 551 F.3d 1030, 1040 (D.C. Cir. 2008); *see, e.g.*, *Freeman v. U.S. Dep't of the Interior*, 37 F. Supp. 3d 313, 344-45 (D.D.C. 2014) (finding that "unappealed" ALJ rulings could not estop the United States because such rulings were not binding on the agency or even on other ALJs and noting that the lack of appeal did not "elevate them to the level of a binding final agency action").

The Ninth Circuit explicitly adopted the reasoning in *Almy*, reversing a district court decision that "incorrectly measured agency inconsistency across" ALJ decisions. *Int'l Rehab. Sci. Inc. v. Sebelius*, 688 F.3d 994, 1001 (9th Cir. 2012); *see also County of Los Angeles v. Leavitt*, 521 F.3d 1073, 1079 (9th Cir. 2008) (noting that "intermediary interpretations are not binding on the Secretary, who alone makes policy"). Likewise, the Seventh Circuit recognized that lower-level decisions may conflict and do not bind the Secretary. *Abraham Memorial Hosp. v. Sebelius*, 698 F.3d 536, 556 (7th Cir. 2012) ("The handful of prior Board decisions the Hospitals rely upon to purportedly show HHS's long-standing policy are not determinative. Our precedent instructs that Board decisions are not the decisions of the Secretary or her Administrator and are not authoritative."); *Homemakers North Shore, Inc. v. Bowen*, 832 F.2d 408, 413 (7th Cir. 1987) ("'The Secretary's position' is the position of the Department as an entity, and the fact that people in the chain of command have expressed divergent views does not diminish the effect of the agency's resolution of those disputes. An inconsistent administrative position means flipflops by the agency over time, rather than reversals within the bureaucratic pyramid."). The Fifth Circuit reached the same conclusion. *See Homan & Crimen, Inc. v. Harris*, 626 F.2d 1201, 1205 (5th Cir. 1980) ("[T]he decision of the [Provider Reimbursement Review Board] carries no more weight on review by the Secretary than any other interim

decision made along the way in an agency where the ultimate decision of the agency is controlling.").

In sum, "Congress has delegated broad authority to the Secretary to determine when a device is reasonable and necessary, as well as broad authority to select the procedures used for making that determination. The decisions of local contractors cannot deprive her of that discretion, *any more than the diverse decisions of district courts or courts of appeals throughout the country could bind the Supreme Court*." *Almy*, 679 F.3d at 311 (emphasis added). The doctrine of collateral estoppel cannot transform an ALJ ruling from what is – a decision by an intermediate-level tribunal that is only binding in a single case – to what it is not – an officially binding statement of policy by the Secretary. To do so would be contrary to the Medicare statute and regulations.

3. Collateral estoppel is contrary to the Medicare Act's presentment and channeling requirements.

Plaintiff's Complaint seeks injunctive relief against the Secretary and a finding that the "Secretary is collaterally estopped from relitigating whether TTFT treatment for Plaintiffs is a covered benefit." Compl. at 1, 10.[15] In *Porzecanski*, the D.C. Circuit recently held that the Medicare statute prohibits a Medicare beneficiary from obtaining "prospective equitable relief mandating that HHS recognize his treatment as a covered Medicare benefit in all future claim determinations." 943 F.3d at 475.

The facts in *Porzecanksi* are remarkably similar to those in the instant case. Porzecanski suffered from a rare, life-threatening condition with no known cure and started on an experimental regimen of a biological product. *Id.* at 476. At the time, there was a dearth of

[15] Plaintiffs' motion does not mention the request for equitable relief contained in the Complaint, and thus abandons it.

scientific testing supporting the product for plaintiff's symptoms; nonetheless, during the course of plaintiff's treatment, the product came to be considered the best available treatment. *Id.* After beginning treatment, Porzecanski remained symptom-free and his physicians recommended that he continue the monthly treatment indefinitely. *Id.* at 476-77. After one of his claims was denied at the ALJ level and the Council did not render a decision within the required time frame, plaintiff filed in federal court. *Id.* at 477. While the federal case was pending, plaintiff continued to submit monthly Medicare claims, which were approved by a QIC or ALJ. *Id.* On appeal of his denied claim, plaintiff sought declaratory and injunctive relief confirming his entitlement to Medicare coverage for the product and requiring the Secretary to provide Medicare benefits. *Id.*

The D.C. Circuit held that plaintiff could not "satisfy § 405(g)'s presentment requirement with respect to future claims because those claims have not yet arisen." *Id.* at 482. Because Medicare claims can only be filed after the medical service has been furnished, and section 405(g) requires appeals from "decision[s]" of the Secretary, the presentment requirement could not be met: "[T]he Secretary has not decided [plaintiff's] future claims because – to state the obvious – none has been submitted." *Id.*

The court also rejected plaintiff's request to *preclude* the Secretary from concluding that the claims on appeal were not covered by Medicare and were not medically necessary – the *identical* relief that Plaintiffs seek here. *Id.* at 482 (finding plaintiff's "strained position" to be "at odds with Supreme Court precedent."). In support, the D.C. Circuit relied on two Supreme Court decisions: *Ringer* and *Illinois Council*. In *Ringer*, "the Court held that § 405(g) barred a patient from obtaining declaratory and injunctive relief compelling the Secretary to conclude that his future surgery was 'reasonable and necessary' under the Medicare Act." *Id.* (citing 466 U.S.

at 620-21). Although the patient sought equitable relief, it was "essentially one requesting the payment of benefits." *Id.* (quoting 466 U.S. at 620). Any claim seeking to establish a right of future payments constitutes a "claim arising under" the Medicare Act. *Id.* (citing 466 U.S. at 621). Likewise, in *Illinois Council*, the Court again declared that a "claim for future benefits is a § 405(h) claim" and that "all aspects" of any future claim "must be channeled through the administrative process." *Id.* (citing 529 U.S. at 12).

The D.C. Circuit thus concluded, "*Ringer* and *Illinois Council* directly foreclose [plaintiff's] attempt to recast the requested relief as anything other than a claim for future benefits." *Id.* at 483. Likewise, Plaintiffs' assertion that the Secretary is estopped from denying their future claims for TTFT treatment "runs headlong into the Supreme Court's instruction that 'all aspects' of a claim be first channeled through the agency." *Id.* (quoting *Illinois Council*, 529 U.S. at 12). Plaintiffs cannot leverage a favorable ALJ decision to estop the Secretary from denying "future claims for the same reasons." *Id.* at 483-84.

4. Collateral estoppel is contrary to the Appropriations Clause of the U.S. Constitution.

The Appropriations Clause of the Constitution, Art. I, § 9, cl. 7, provides that: "No Money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law." In *Office of Personnel Management v. Richmond*, 496 U.S. 414 (1990), the Supreme Court held that the government, despite the erroneous oral and written representations of a federal employee, was not equitably estopped from determining that a claimant who exceeded the statutory limit on earnings was ineligible for disability benefits. The Supreme Court concluded:

> Whether there are any extreme circumstances that might support estoppel in a case not involving payment from the Treasury is a matter we need not address. As for monetary claims, it is enough to say that this Court has never upheld an assertion of estoppel against the Government by a claimant seeking public funds. In this context, there can be no estoppel, for courts cannot estop the Constitution.

Id. at 434. *See also Genesis Health Ventures, Inc. v. Sebelius*, 798 F. Supp. 2d 170, 183 (D.D.C. 2011) ("[N]either the Supreme Court nor our Court of Appeals has ever upheld "an estoppel claim against the Government 'for the payment of money.'") (citing *Richmond*, 496 U.S. at 427).

Courts have applied the holding in *Richmond* to the Medicare context. In *Monongahela Valley Hosp., Inc. v. Sullivan*, 945 F.2d 576 (3d Cir. 1991), the Third Circuit held that *Richmond* foreclosed a Medicare provider's estoppel claim against the Secretary for additional Medicare reimbursement. *Id.* at 588-89. Likewise, in *Downtown Medical Center/Comprehensive Health Care Clinic v. Bowen*, the Tenth Circuit declined to estop the Secretary and a private insurer, which processed Medicare claims on the Secretary's behalf, from denying the plaintiff's reimbursement claim. 944 F.2d 756, 771 (10th Cir. 1991). *See also Almy*, 679 F.3d at 312 ("It is the Secretary, not the courts, who bears the responsibility for the disbursement of billions of dollars of public money under the Medicare system.").

The same reasoning applies to Plaintiffs' assertion of collateral estoppel. Plaintiffs seek to estop the Secretary from denying their claims payment from the Medicare Trust Fund. Of course, no appropriation of Congress entitles Plaintiffs to future payments from the Medicare Trust Fund. Because Plaintiffs seek to draw money from the Treasury on equitable grounds, the Court must deny their assertion of collateral estoppel.

5. The elements of collateral estoppel are not present here.

The Third Circuit has identified four required elements for the application of collateral estoppel: "(1) the identical issue was previously adjudicated; (2) the issue was actually litigated; (3) the previous determination was necessary to the decision; and (4) the party being precluded from relitigating the issue was fully represented in the prior action." *Jean Alexander Cosmetics, Inc. v. L'Oreal USA, Inc.*, 458 F.3d 244, 249 (3d Cir. 2006) (internal quotations omitted). The

Third Circuit considers whether the party being precluded "had a full and fair opportunity to litigate the issue in question in the prior action, . . . and whether the issue was determined by a final and valid judgment." *Id.* (internal quotation marks and citations omitted). Third Circuit courts also require that the adjudicator at the prior proceeding confronted and decided the question, not merely remarked on it in dicta. *See Khalil v. Rohm & Haas Co.*, 2008 WL 383322, at *14 (E.D. Pa. Feb. 11, 2008) (citing *Hawksbill Sea Turtle v. Fed. Emergency Mgmt. Agency*, 126 F.3d 461, 465 (3d Cir. 1997)).).

As noted above, collateral estoppel cannot apply as to Plaintiff Lewis, because the unfavorable decision on appeal here (dated May 30, 2019) *predates* his favorable ALJ decision (dated October 24, 2019). *See supra* § IV.A. Nor does collateral estoppel apply as to either Plaintiff, because the first, second, and fourth elements of collateral estoppel are not met.

First, the issues decided in Plaintiffs' claim appeals were different, because they each concerned whether TTFT treatment was covered under Medicare for a *specific period in time*. *See* Pl. Br. at 5 ("Each claim for Medicare coverage concerns only the one to three months at issue for that claim."). Notably, both the ALJ who denied Oxenberg's treatment and the ALJ who approved her treatment limited their "Conclusions of Law" to specific coverage dates. *See* Ex. A to Pl. Br. at 6 (6/3/19 Favorable Decision) (approving coverage for dates of service from July-October 2018); CAR at 110 (9/5/19 Unfavorable Decision) (denying coverage for dates of service from April-June 2018). Likewise, the ALJs who decided Lewis' claims limited their "Conclusions of Law" to specific coverage dates. *See* CAR at 840 (5/3/19 Unfavorable Decision); Ex. F to Pl. Br. at 4 (10/24/19 Favorable Decision). Because the favorable ALJ decisions did not adjudicate whether Medicare coverage existed for any other claims, much less the claims simultaneously on appeal before another ALJ, the first element of collateral estoppel

is not present.[16] *See, e.g.*, *Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 435 F.3d 1356, 1361-62 (Fed. Cir. 2006) (declining to apply collateral estoppel where patent infringement involved two distinct time periods).

Furthermore, the issues decided in Plaintiffs' favorable and unfavorable ALJ decisions were substantially different. In the favorable ruling for Oxenberg, the ALJ declined to apply the LCD without conducting a review of its validity. *See* Ex. A. to Pl. Br. at 5-6. In the unfavorable ruling, however, Oxenberg improperly asked the ALJ to set aside the LCD. CAR at 108-110. Accordingly, the ALJ denied her claim on the basis that a claim appeal is not the proper forum for challenging the validity of the LCD. *Id.*; 42 C.F.R. § 405.1062(c) (an ALJ does not have authority to "set aside" or "review the validity" of an LCD in a claim appeal). Likewise, Lewis' unfavorable decision stemmed from his improper request to set aside the LCD (CAR at 838-39), while a subsequent decision approved his claim without discussing the LCD's validity (Ex. F. to Pl. Br. at 3-4). Several courts have noted that the regulations forbid ALJs from setting aside an LCD in the context of a claim appeal.[17]

Plaintiffs, however, were not without recourse and could have challenged the LCD or petitioned CMS for a National Coverage Determination under entirely separate channels of review. *See* 42 U.S.C. § 1395y(l) (describing the process of requesting an NCD); 42 C.F.R. §

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[16] Even if the favorable decision had addressed Medicare coverage for other time periods – which it did not – that discussion would be mere dicta and insufficient for the application of collateral estoppel. *See Khalil*, 2008 WL 383322, at *14.

[17] *See Odell v. Azar*, 344 F. Supp. 3d 1192, 1198, 1202 (D. Nev. 2018) (noting that plaintiff "can appeal an individual claim as a supplier, but an ALJ or the Council cannot review the validity of an LCD for purposes of a claim appeal."); *Medicomp, Inc. v. HHS*, 2016 WL 901282, at *6-7 (M.D. Fla. Mar. 3, 2016) (finding that plaintiff's presentation of clinical or scientific evidence at the ALJ level constituted a challenge to the LCD's validity and noting that ALJs do not have authority to set aside an LCD in a claim appeal).

426.425 (only by raising an LCD challenge can an aggrieved party "state why the LCD is not valid"); *Porzecanksi*, 943 F.3d at 486 ("There is a distinct path provided for beneficiaries to secure broader coverage determinations and [plaintiff] cannot circumvent those procedures"), 486 n.12 (explaining the distinct channels for challenging an LCD versus filing a claim appeal).[18] Because the unfavorable ruling was based upon Plaintiffs' improper challenge to the LCD in a claim appeal – an issue that was not even presented, much less decided, in the favorable decision – collateral estoppel does not apply.

Second, the favorable ALJ ruling did not involve any litigation as to whether Medicare coverage existed for any other time periods. Indeed, the Secretary was not a party to Plaintiffs' favorably decided appeals, which, by itself, militates against the application of collateral estoppel. Exs. A-C, F to Pl. Br.; *see, e.g., Weinstein v. Islamic Rep. of Iran*, 175 F. Supp. 2d 13, 21 (D.D.C. 2001) (declining to apply collateral estoppel where defendants failed to make an appearance).

As to the fourth element, the Secretary has a limited opportunity to litigate Medicare coverage appeals. Indeed, the Secretary has no opportunity to participate during the first (redetermination) and second (QIC) levels of the administrative appeal process. *See* 42 C.F.R. §§ 405.948, 405.968. It would obviously be improper to find that the Secretary had a "full and fair" opportunity to participate under those circumstances. *See Genesis Health*, 798 F. Supp. 2d at 182 ("[I]f an intermediary finds coverage and pays a claim, there is never an administrative

[18] A beneficiary may challenge an LCD before receiving an item or service or after the LCD has been applied, resulting in a coverage denial. 68 Fed. Reg. 63692, 63693-94 (Nov. 7, 2003). "[A] successful challenge would permit the individual to have his or her specific claim reviewed without reference to the challenged policy." *Id.* In other words, Plaintiffs had the opportunity to seek coverage for their claims by challenging the LCD, but opted instead to pursue the narrower relief available in a claim appeal.

appeal, and the Secretary would have no knowledge of the intermediary's decision nor opportunity to review those actions.").

The Secretary has a limited opportunity to litigate ALJ appeals. If the beneficiary is unrepresented, then the Secretary cannot be a party to the hearing, and thus has no opportunity to litigate. 42 C.F.R. § 405.1012(a). Furthermore, if the Secretary does not affirmatively elect to participate or become a party in ALJ proceedings, the proceedings simply move forward without the Secretary's involvement. 42 C.F.R. §§ 405.1010(a), 405.1012(b). Although the Secretary may participate or become a party in ALJ hearings involving beneficiaries represented by counsel, it is impracticable for the Secretary to litigate hundreds of thousands of appeals annually. 42 C.F.R. §§ 405.1010(a), 405.1012; *see supra* n.2.

If the Secretary does not become a party to an ALJ hearing, it cannot appeal a favorable ruling to the Council. 42 C.F.R. §§ 405.1012, 405.1102(a)(1), (d). In other words, the Secretary would need to litigate every ALJ hearing in order to have the right to appeal any decisions favorable to the beneficiary. Because the Secretary's opportunity to appeal was also extremely limited, it did not have the full and fair opportunity to litigate. *See DePolo v. Bd. of Supervisors of Tredyffrin Twp.*, 835 F.3d 381, 387 (3d Cir. 2016) ("We have explained that 'in determining whether a litigant has been given a 'full and fair' opportunity to litigate a claim, we must take into account the possibility of appellate review' because a full and fair opportunity to litigate 'includes the possibility of a chain of appellate review.'") (quoting *Crossroads Cogeneration Corp. v. Orange & Rockland Utils., Inc.*, 159 F.3d 129, 137 (3d Cir. 1998)).

6. It would be unfair to apply collateral estoppel offensively against the Secretary.

The Supreme Court has granted district courts "broad discretion" to determine when a plaintiff who has met the requisites for the application of collateral estoppel may employ that

doctrine offensively. *See Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 331 (1979). The Court explained:

> If a defendant in the first action is sued for small or nominal damages, he [or she] may have little incentive to defend vigorously, particularly if future suits are not foreseeable. . . . [If] the application of offensive estoppel would be unfair to a defendant, a trial judge should not allow the use of offensive collateral estoppel.

Id. at 330–31 (citations omitted). Under Third Circuit law, a "finding of fairness to the defendant is thus a necessary premise to the application of offensive collateral estoppel." *Raytech Corp. v. White*, 54 F.3d 187, 195 (3d Cir. 1995).

The Supreme Court has never upheld the application of offensive collateral estoppel against the United States, and "it is well-settled that the Government may not be estopped on the same terms as any other litigant." *Community Health Servs.*, 467 U.S. at 60. The seminal case on point is *United States v. Mendoza*, 464 U.S. 154 (1984). In *Mendoza*, the Court held that the "United States may not be collaterally estopped on an issue . . . adjudicated against it in an earlier lawsuit brought by a different party." *Id.* at 155. The Court distinguished *Parklane Hosiery*, 439 U.S. 322 (1979), holding that "nonmutual collateral estoppel is not be extended to the United States." *Id.* at 159. The Court's decision stemmed from its recognition that "'the Government is not in a position identical to that of a private litigant,' both because of the geographic breadth of government litigation and also, most importantly, because of the nature of the issues the government litigates." *Id.* (quoting *INS v. Hibi*, 414 U.S. 5, 8 (1973) (per curiam)).

The Court noted that the government is "party to a far greater number of cases on a nationwide basis than even the most litigious private entity." *Id.* The government is likely to be involved in lawsuits against different parties that involve the same legal issues – issues that are frequently of substantial public importance. *Id.* at 160. Accordingly, allowing non-mutual

collateral estoppel "would substantially thwart the development of important questions of law by freezing the first final decision rendered on a particular legal issue." *Id.* Rather than receiving the benefit of several courts of appeal decisions, the Supreme Court could only review one final decision before granting certiorari. *Id.*

In addition, the Court approved of the Solicitor General's discretion when determining whether to appeal. Unlike a private litigant, the Solicitor General "considers a variety of factors, such as the limited resources of the government and the crowded dockets of the courts, before authorizing an appeal." *Id.* at 161. On the other hand, if non-mutual estoppel applied against the Government, the Solicitor General would have to "abandon those prudential concerns and . . . appeal every adverse decision in order to avoid foreclosing further review." *Id.* The Court concluded that "[t]he conduct of government litigation in the courts of the United States is sufficiently different from the conduct of private civil litigation in those courts so that what might otherwise be economy interests underlying a broad application of collateral estoppel are outweighed by the constraints which peculiarly affect the government." *Id.* at 162-63; *see also Jones v. Ashcroft*, 321 F. Supp. 2d 1, 6 (D.C. Cir. 2004) (noting that "a plaintiff generally may not apply offensive collateral estoppel against the government.").

The policy reasons against collaterally estopping the United States apply with particular force here. As in *Parklane* and *Mendoza*, it would not be practicable for the Secretary to defend himself in the over 400,000 ALJ appeals filed each year. Accordingly, the Secretary generally devotes his resources to administering payment of Medicare claims. Nor would the Secretary have any reason to believe that a favorable ALJ ruling could have preclusive effect in future claims, because that outcome would be contrary to the Medicare statute and regulations, Supreme Court precedent, and a number of circuit-level decisions. *See supra* §§ IV.B.1-2. The

Medicare appeals process explicitly permits ALJs to reach varying conclusions, and gives the Council discretion to impose uniformity by issuing precedential decisions. As with federal courts, allowing conflicting decisions to percolate up to a higher level improves the decision-making process. *See Mendoza*, 464 U.S. at 160. Finding that an ALJ decision deprives the Secretary of discretion when to make a final determination would be akin to finding that a district court decision could bind the Supreme Court. *See Almy*, 679 F.3d at 310.

The Medicare appeals process is particularly unsuited to the application of collateral estoppel. In *Porzecanksi*, the D.C. Circuit held that "stretch[ing] the outcome of a single claim dispute to foreclose a contrary decision in any future determination . . . is at odds with the Medicare regime. . . . Medical science changes. An accepted practice may be obsolete in a few years. Ordering HHS to cover [plaintiff's] treatments indefinitely can hardly be necessary to effectuate the district court's judgment regarding one treatment at a particular point in time." 943 F.3d at 486. Likewise, the Fourth Circuit concluded that plaintiff's "proposed expansion of what constitutes binding agency precedent would severely constrict the undisputed delegated authority of the Secretary to administer the Medicare system." *Almy*, 749 F.3d at 310. The court continued:

> [Plaintiff] seeks to impose massive resource costs on the Secretary, requiring her to reverse any decision at a lower level of adjudication either through promulgation of an NCD or through [Council] review lest that lower decision become precedent that precludes a different considered result in future cases before the [Council]. As the Secretary notes, there were 970 million Medicare Part B claims in 2008 alone, and the Secretary rarely participates in the lower level adjudications of those claim determinations. . . . The Secretary has simply not seen fit to invoke her final authority in every case in which there is an argument over whether the evidence adequately supports a finding that a device was "reasonable and necessary."

Id. at 311 (citations omitted). Accordingly, even assuming that collateral estoppel were legally supportable – which it is not – as a matter of policy, the doctrine of collateral estoppel has no place in Medicare claims appeals and would impose massive costs upon this critical national program and undermine its mission to support the health of the tens of millions of Americans who are Medicare beneficiaries.

The fairness element is also lacking because collateral estoppel could only run against the Secretary – not against the beneficiary. While denial of a beneficiary's claim has no effect on any future claim, under Plaintiffs' proposal, a single claim approval would forever estop the Secretary from denying future claims. Contrary to decades of Supreme Court precedent, the United States would be *more* susceptible to collateral estoppel than would private litigants. Because the application of collateral estoppel would be fundamentally unfair to the Secretary, it should not be applied here.

7. Even if collateral estoppel applied, it would have no force after the new LCD became effective on September 1, 2019.

Even if collateral estoppel applied here, which it surely does not, it would have no force after the new LCD became effective on September 1, 2019. Collateral estoppel generally will not apply when "'controlling facts or legal principles have changed significantly since the [prior] judgment.'" *Karns v. Shanahan*, 879 F.3d 504, 514 (3d Cir. 2018) (alteration in original) (quoting *Montana*, 440 U.S. at 155. Here, there is no doubt that there was a significant change between the old LCD, which categorically denied coverage for TTFT treatment, and the new LCD, which allowed coverage of TTFT under certain circumstances. Accordingly, if Plaintiff were to prevail on collateral estoppel, the only decision that might be estopped would be the September 5, 2019 decision denying Oxenberg's treatment. Further preclusive or injunctive

relief would not be warranted, because the new LCD has already been in place for over six months.

Along the same lines, the medical context of this case necessarily means that the controlling facts are constantly changing. Physicians do not prescribe treatment, no matter how potentially effective, *indefinitely* into the future. A treatment that may have been beneficial for a patient at one point in time could be ineffective or dangerous if continued (*e.g.*, when a patient suffers serious side effects). In this case, there is no evidence that the facts supporting Plaintiffs' claims for coverage in 2018 are identical to the facts supporting their claims for coverage in 2020. Even if their medical history remained unchanged for two years, it would be pure speculation to assert that the facts would remain unchanged for any claim they might file in the future. For example, if Plaintiffs filed claims for coverage, but the evidence showed that they were not actually using the device, Medicare should not be required to approve their claims. *See* CAR at 136 (2019 LCD requires that a beneficiary "use TTFT for an average of 18 hours per day").

Because the controlling facts and law have changed, applying collateral estoppel would have zero benefit for Plaintiffs, who are not financially responsible for the claims on appeal. Meanwhile, a finding that favorable ALJ decisions have preclusive effect would have widespread, negative ramifications for the Medicare program, and the many million Americans it serves. Because collateral estoppel is fundamentally inconsistent with the Medicare Program, the Court should grant summary judgment for the Secretary.

V. CONCLUSION

For the foregoing reasons, the Secretary respectfully requests that the Court grant his cross-motion for summary judgment and deny Plaintiffs' motion for summary judgment.

Respectfully submitted,

WILLIAM M. McSWAIN
United States Attorney

/s/ Susan R. Becker
for Gregory B. David
GREGORY B. DAVID
Assistant United States Attorney
Chief, Civil Division

/s/ Eric S. Wolfish
ERIC S. WOLFISH
Special Assistant United States Attorney/
Assistant Regional Counsel, HHS
Eric.Wolfish@hhs.gov

/s/ Matthew E. K. Howatt
MATTHEW E. K. HOWATT
Assistant United States Attorney
United States Attorney's Office
615 Chestnut Street, Suite 1250
Philadelphia, PA 19106
Tel: 215-861-8335
Fax: 215-861-8618
Matthew.Howatt@usdoj.gov

Dated: April 20, 2020

CERTIFICATE OF SERVICE

I hereby certify that on this day, I caused a true and correct copy of the foregoing cross-motion for summary judgment to be served on all counsel of record via the Court's CM/ECF system.

/s/ Matthew E. K. Howatt
MATTHEW E. K. HOWATT
Assistant United States Attorney

Dated: April 20, 2020

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

MAUREEN PIEKANSKI *Plaintiff,* v. ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services, *Defendant.*	No. 3:20-CV-00687 (Judge Mariani) (Magistrate Judge Carlson) (Electronically Filed)

DEFENDANT'S MEMORANDUM OF LAW IN SUPPORT OF HIS CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

DAVID J. FREED
United States Attorney

ERIC S. WOLFISH
Special Assistant United States Attorney
United States Department of Health
and Human Services
Office of the General Counsel, Region III
801 Market Street, Suite 9700
Philadelphia, PA 19107-3134
(215) 861-4511
eric.wolfish@hhs.gov

NAVIN JANI
Assistant U.S. Attorney
228 Walnut Street
Suite 220
Harrisburg, PA 17108
(717) 221-4482
navin.jani@usdoj.gov

Attorneys for Defendant

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I. <u>INTRODUCTION</u>

Plaintiff Maureen Piekanski suffers from a terrible and deadly form of brain cancer, glioblastoma multiforme ("GBM"). This case involves judicial review of the denial of a Medicare claim for certain months of tumor treatment field therapy ("TTFT") to treat GBM.[1] Plaintiff raises a single issue on appeal: whether the Secretary of the Department of Health and Human Services (the "Secretary") is collaterally estopped from denying Plaintiff's TTFT claim because an administrative law judge ("ALJ") allowed coverage for certain months of TTFT. But Plaintiff is simply wrong on the law: there is no collateral estoppel here.

Although Plaintiff asserts offensive collateral estoppel against the Secretary, the applicable Medicare statute and regulations expressly prohibit ALJ decisions from having any preclusive effect in future cases. *See, e.g.*, 42 U.S.C. § 1395ff(d)(2)(B); 42 C.F.R. § 405.1062(b). Indeed, the case that Plaintiff principally relies upon in support of collateral estoppel held that preclusion cannot apply when there is a statutory purpose to the contrary, as there is here. *See Astoria Fed. Sav. & Loan Ass'n v. Solimino*, 501 U.S. 104, 108 (1991). The Third Circuit held that the highest level of administrative review, the Medicare Appeals Council ("Council"), "is free to depart from these lower level agency rulings [from

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[1] Plaintiff is not financially responsible for paying for the TTFT claim at issue if Medicare does not cover it. *See infra* § II.F.

QICs and ALJs] without concern, as *only its decisions have legal significance*." *Taransky v. Sec. U.S. Dep't of Health & Human Servs.*, 760 F.3d 307, 319 (3d Cir. 2014) (emphasis added); *see also John Balko & Assocs., Inc.*, 555 F. App'x 188, 193 (3d Cir. 2014) (holding that the Council's "review of the ALJ's findings is *de novo* and [the Council] *is not obligated to defer to the outcomes of prior decisions below*.") (emphasis added and citation omitted). These Third Circuit holdings directly refute Plaintiff's collateral estoppel argument, and the Fourth, Fifth, Seventh, Ninth, and D.C. Circuits have also rejected Plaintiff's assertion that lower-level administrative decisions bind federal agencies. An ALJ decision does not bind the Council just as a district court decision does not bind the Supreme Court. *See Almy v. Sebelius*, 679 F.3d 297, 310 (4th Cir. 2012).

Furthermore, the elements of collateral estoppel are not present here. First, identical issues were neither previously adjudicated nor actually litigated in Plaintiff's claim appeals, which concern Medicare coverage for TTFT during different time periods. Second, the controlling facts and legal principles changed significantly in the time between Plaintiff's claim appeals were decided. Third, it would be unfair to apply collateral estoppel offensively against the Secretary, which was not a party to Plaintiff's claim appeals. Indeed, it is impracticable for the Secretary to appear as a party in thousands of Medicare claim appeals that are filed each year at the ALJ level. A finding that favorable ALJ decisions

collaterally estop the Secretary would have widespread, negative ramifications for the Secretary and Medicare beneficiaries. The Secretary would be forced to devote Medicare resources to actively litigate thousands of ALJ appeals to avoid the risk of collateral estoppel, thereby taking resources away from tens of millions of Medicare beneficiaries.

Plaintiff fails to identify any case holding that an ALJ's claim determination is binding upon the Secretary in future cases for the same treatment. Meanwhile, the Eastern District of Wisconsin, considering an identical TTFT claim appeal, recently rejected Plaintiff's collateral estoppel argument. *See Christenson v. Azar*, 2020 WL 3642315 (E.D. Wis. July 6, 2020). Because the application of collateral estoppel to ALJ decisions is contrary to the Medicare statute and regulations, Supreme Court precedent, and numerous circuit-level decisions, summary judgment should be granted in the Secretary's favor and Plaintiff's motion for summary judgment should be denied.[2]

II. STATUTORY AND REGULATORY BACKGROUND

A. "Reasonable and Necessary" Medicare Expenses

Medicare is a federal health insurance program for people who are elderly and/or have disabilities. *See* 42 U.S.C. § 1395. For a medical service to be

[2] Plaintiff's summary judgment motion only raises the issue of collateral estoppel. Because Plaintiff has abandoned any other grounds to challenge the ALJ decision at issue, the Secretary does not address them.

covered by Medicare, it must fit within a benefit category established by the Medicare statute. *Id*.

This case concerns Medicare Part B, which extends coverage to certain types of durable medical equipment ("DME") for qualified recipients. 42 U.S.C. §§ 1395k(a), 1395x(s)(6). The various benefit categories available under Medicare Part B are set forth in 42 C.F.R. part 410. Almost all Medicare coverage determinations, including those in this case, are subject to 42 U.S.C. § 1395y(a)(1)(A), which excludes certain items from coverage. Under this section, "no payment may be made under . . . part B of this subchapter for any expenses incurred for items or services[] which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member . . . ." 42 U.S.C. § 1395y(a)(1)(A). Unless there is an exception, this bar applies "[n]othwithstanding any other provision" of the Medicare statute. 42 U.S.C. § 1395y(a)(1)(A). The Centers for Medicare & Medicaid Services ("CMS"), which administers the Medicare program for the Secretary, has historically interpreted "reasonable and necessary" to mean that an item or service must be safe and effective, medically necessary and appropriate, and not experimental in order to qualify for reimbursement. *See* Medicare

Program Integrity Manual ("MPIM") § 13.5.1.[3]

To administer the "reasonable and necessary" standard, the Secretary employs a range of tools, from formal regulations to informal manuals. In choosing among these options, the Secretary is not required to promulgate regulations or policies that, "either by default rule or by specification, address every conceivable question" that may arise. *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 96 (1995). The Secretary may articulate "reasonable and necessary" standards through formal regulations that have the force and effect of law throughout the administrative process. *See* 42 U.S.C. §§ 1395hh; 1395ff(a)(1). The Secretary may also issue National Coverage Determinations ("NCDs") "with respect to whether or not a particular item or service is covered nationally." 42 U.S.C. § 1395ff(f)(1)(B); *see also* 42 C.F.R. §§ 400.202, 405.1060.

B. Enforcement of the "Reasonable and Necessary" Standard Through Local Coverage Determinations ("LCDs")

The Secretary has delegated to CMS broad authority to determine whether

[3] All citations are to the version of the MPIM in effect at the time the 2014 LCD (defined in § II.D.) was issued, which is available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R473PI.pdf (Transmittal 473, dated 6/21/2013). The MPIM "is a compilation of guidelines which CMS issues to instruct Medicare contractors on how to conduct medical review of Medicare claims submitted by Medicare providers and suppliers for payment." *Erringer v. Thompson*, 371 F.3d 625, 628 (9th Cir. 2004).

Medicare covers particular medical services.[4] CMS, in turn, contracts with Medicare Administrative Contractors ("MACs"), such as Noridian Healthcare Solutions in this case, to administer certain day-to-day functions of the Medicare program. 42 U.S.C. § 1395kk-1. Consistent with controlling regulations and NCDs, a MAC makes coverage determinations, issues payments, and develops LCDs for the geographic area it serves, *see* 42 U.S.C. § 1395ff(f)(2)(B), in accordance with the reasonable and necessary provisions in 42 U.S.C. § 1395y(a)(1). *See* 42 U.S.C. §§ 1395kk-1(a)(4), 1395ff(f)(2)(B). An LCD is binding only on the contractor that issued it, and only at the initial stages of the Medicare claim review process, as opposed to later stages if a claimant should appeal a determination by a MAC. 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II).

In developing LCDs, such as the one at issue in this case, MACs follow guidance contained in the MPIM. The MPIM requires MACs to publish LCDs that specify when "an item or service is considered to be reasonable and necessary." MPIM § 13.1.3. MACs develop LCDs by "considering medical literature, the advice of local medical societies and medical consultants, public comments, and comments from the provider community." *Id.*; 66 Fed. Reg. 58,788, 58,788 (Nov. 23, 2001). MACs also follow detailed procedures for issuing new or substantively revised LCDs, including engaging in a comment-and-notice period, soliciting

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4 *See* 42 U.S.C. §§ 1395y(a), 1395ff(a), (f).

feedback and recommendations from the medical community, and presenting the policy in meetings of stakeholders. MPIM § 13.7.4.

C. The Process of Promulgating LCDs

New LCDs require both a notice period and a comment period. MPIM § 13.7.2. The MAC first issues a draft LCD and provides the public a minimum of 45 days to comment on it. LCDs are based on the strongest evidence available, which, in order of preference, includes: (1) Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies; and (2) General acceptance by the medical community (standard of practice), as supported by sound medical evidence. MPIM § 13.7.1. Sound medical evidence should include: (a) scientific data or research studies published in peer-reviewed medical journals; (b) consensus of expert medical opinion (i.e., recognized authorities in the field); or (c) Medical opinion derived from consultations with medical associations or other health care experts. MPIM § 13.7.1. After considering all of the comments and revising the LCD as needed, the contractor publishes the final LCD. *Id.* at § 13.1.3.

D. The LCD for TTFT Devices

In April 2011, the United States Food and Drug Administration approved the marketing of the NovoTTF-100A device (later rebranded Optune) manufactured and supplied to beneficiaries by Novocure, for the treatment of recurrent GBM.

Administrative Record ("AR") at 2506 [Dkt. No. 33]. Following an open meeting and solicitation of public comments, in August 2014, the MACs issued the original LCD for TTFT (the "2014 LCD"). *Id.* "The DME MACs determined that, based on the strength and quality of the evidence available at that time, TTFT was not reasonable and necessary for the treatment of GBM." *Id.* The 2014 LCD was in effect at the relevant time, *i.e.*, during the dates of service for the claims on appeal, remained substantively unchanged, and stated that "Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary." *Id.*; AR at 2577.

In 2018, Novocure requested that the DME MACs approve Medicare payment of TTFT for newly diagnosed GBM. AR at 2506.[5] Effective September 1, 2019, the LCD was revised to permit coverage for newly diagnosed GBM and continued coverage for newly diagnosed GBM beyond the first three months of therapy in certain circumstances. AR at 2501-02. Novocure was "extremely pleased" with the 2019 LCD and notes that its coverage criteria "is generally similar to Optune's commercial coverage criteria for newly diagnosed GBM."[6]

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[5] Novocure did not submit new evidence in support of revised coverage for recurrent GBM, which was not covered. *Id.*

[6] *See* Medicare Releases Final Local Coverage Determination Providing Coverage of Optune® for Newly Diagnosed Glioblastoma, https://www.novocure.com/medicare-releases-final-local-coverage-determination-providing-coverage-of-optune-for-newly-diagnosed-glioblastoma/ (last visited August 27, 2020).

E. Claims and Administrative Appeals

In order for a beneficiary to challenge a denial of a claim under the Medicare statute, he or she must submit a claim for payment to the Medicare contractor, and if the claim is denied, the beneficiary must generally exhaust four levels of administrative review before filing suit in district court. *See generally* 42 U.S.C. § 1395u(a); 42 C.F.R. § 405.904. First, the beneficiary may seek a redetermination from the Medicare contractor, which must be performed by a person who did not make the initial decision. 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. §§ 405.920, 405.940. An LCD is binding only at this first level of review, and is not binding at any higher level of review 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II); 42 C.F.R. § 405.968(b). At the second level, a beneficiary may seek reconsideration by a qualified independent contractor ("QIC") whose panel members must have "sufficient medical, legal, and other expertise, including knowledge of the Medicare program." 42 U.S.C. § 1395ff(b)(1)(A), 1395ff(c); 42 C.F.R. §§ 405.960, 405.968(c)(1). At the third level, a beneficiary can request a hearing before an ALJ, who issues a decision based on the evidence presented at the hearing or otherwise admitted into the administrative record by the ALJ. 42 U.S.C. § 1395ff(b)(1)(A), 1395ff(d); 42 C.F.R. §§ 405.1000-02, 405.1042, 405.1046.

The administrative process ends in a review of the ALJ's decision by the Council, a division of the Departmental Appeals Board of the Department of

Health and Human Services. 42 U.S.C. § 1395ff(b)(1)(A), (d)(2); 42 C.F.R. §§ 405.1100, 405.1122. The Council's decision (or the ALJ decision, if not reviewed by the Council) represents the final decision of the Secretary for purposes of administrative exhaustion. 42 U.S.C. § 1395ff(b)(1)(A), (d)(2)(A); 42 C.F.R. §§ 405.1048, 405.1130, 405.1136. If the Council does not render a decision within a specified time frame, a beneficiary may request elevation to district court. 42 C.F.R. § 405.1132.

The claimant is entitled to judicial review of the Secretary's decision in the district court "as is provided in [42 U.S.C.] 405(g)." 42 U.S.C. § 1395ff(b)(1)(A). In such review, the Secretary's findings of fact "if supported by substantial evidence, shall be conclusive." 42 U.S.C. § 405(g).

F. Advance Beneficiary Notices

If Medicare coverage is denied, Medicare will nevertheless pay the claim if neither the supplier nor the beneficiary knew or could reasonably have been expected to know that the item would not be covered. 42 U.S.C. § 1395pp; 42 C.F.R. § 411.400(a). The supplier can shift the risk of non-coverage to the beneficiary by providing her with advance written notice (called an "Advance Beneficiary Notice") of the specific reason why the item probably will not be covered. 42 C.F.R. § 411.404(b). As the ALJ found, because Novocure did not require Plaintiff to sign an Advance Beneficiary Notice, no matter the outcome of

this case, she will not be financially responsible for the TTFT claim at issue. AR at 2578.

III. PROCEDURAL HISTORY

On January 18, 2019, ALJ Glaze denied Plaintiff's claim for Medicare coverage of certain months of treatment with the Optune system for her GBM. AR at 2578. Plaintiff has fully exhausted her administrative remedies, because the ALJ decision denying her claim became final when the Council did not timely respond to her notice of escalation. AR at 2446-47. Plaintiff filed the instant action instead of awaiting a hearing before the Council. *Id.*

IV. STANDARD OF REVIEW

For appeals arising under section 405(g), a court must uphold an ALJ's findings if they are supported by substantial evidence. *See McGinnis v. Social Security Admin.*, 2020 WL 1623703, at *2 (3d Cir. Apr. 2, 2020); *Rutherford v. Barnhart*, 399 F.3d 546, 552 (3d Cir. 2005). Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Rutherford*, 399 F.3d at 552 (citation omitted). It is "more than a mere scintilla but may be somewhat less than a preponderance of the evidence." *Id*. (citation omitted). Review under Section 405(g) is plenary as to the Secretary's application of the relevant law. *Krysztoforski v. Chater*, 55 F.3d 857, 858 (3d Cir.1995).

V. ARGUMENT

A. The Common Law Doctrine of Collateral Estoppel is Inapplicable to ALJ Decisions in Medicare Claim Appeals

1. ALJ decisions expressly do not bind the Secretary in future cases.

Although Plaintiff primarily bases her collateral estoppel argument on a passage from the U.S. Supreme Court decision in *Astoria*, Pl. Br. at 4-5,[7] she tellingly omits the very next paragraph, which explains that preclusion cannot apply when there is a statutory purpose to the contrary: "Courts do not, of course, have free rein to impose rules of preclusion, as a matter of policy, when the interpretation of a statute is at hand[,] ... [and] the question is not whether administrative estoppel is wise but whether it is intended by the legislature." 501 U.S. at 108. The Third Circuit has also held that collateral estoppel may not be applied if it would "frustrate congressional intent or impede the effective functioning of the agency." *Duvall v. Atty. Gen. of U.S.*, 436 F.3d 382, 387-88 (3d Cir. 2006) (citing *Astoria* at 108-11). Here, the Medicare statute and regulations

[7] In *Astoria*, the Court considered whether claimants alleging age discrimination under federal law are "collaterally estopped to re-litigate in federal court the judicially unreviewed findings of a state administrative agency made with respect to an age-discrimination claim." 501 U.S. at 106. The Court held that the state court's findings had no preclusive effect on federal proceedings. *Id.* Because the federal government was not a party, and the Court found the *absence* of estoppel, Plaintiff's cited language is mere dicta.

clearly bar the application of collateral estoppel to ALJ decisions.[8]

The Medicare regulations sharply distinguish between a narrow category of precedential decisions that are binding on future administrative appeals and the remainder of non-precedential decisions that are not binding. Only Council-level decisions have the potential to become precedential, which occurs only if they are so designated by the Chair of the Departmental Appeals Board. 42 C.F.R. § 401.109. Council decisions designated as precedential must be made available to the public, with personally identifiable information removed, and notice of precedential decisions must be published in the Federal Register. 42 C.F.R. § 401.109(b). That decision is then given "precedential effect" and is binding on "all HHS components that adjudicate matters under the jurisdiction of CMS." *Id.* § 401.109(c).[9]

It is undisputed that no Council decision, much less one designated as precedential, has favorably decided Plaintiff's claims. Accordingly, nothing in the Medicare statute or regulations binds the Secretary to approve Plaintiff's TTFT treatment. *See Almy*, 679 F.3d at 310 (finding that the Secretary could not have departed from prior precedent because there were no Council-level decisions

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[8] Plaintiff's reliance on *B & B Hardware, Inc. v. Hargis Indus., Inc.*, is also misplaced, Pl. Br. at 5, because the case involved private parties, and the Court did not consider whether the federal government may be bound by administrative decisions. 575 U.S. 138 (2015).

[9] HHS is the United States Department of Health and Human Services.

finding that the device at issue was "reasonable and necessary" or "safe and effective").

ALJ decisions, in contrast, are not capable of having any "precedential effect." The Medicare regulations define "precedential effect" to mean that:

> (1) Legal analysis and interpretation of a Medicare authority or provision is binding and must be followed in future determinations and appeals in which the same authority or provision applies and is still in effect; and
>
> (2) Factual findings are binding and must be applied to future determinations and appeals involving the same parties if the relevant facts are the same and evidence is presented that the underlying factual circumstances have not changed since the issuance of the precedential final decision.

Id. § 401.109(d). Because the lack of "precedential effect" means that any factual findings or legal analysis in ALJ decisions are not binding in future cases, a favorable ALJ decision has no preclusive effect on any future claim. *See* 42 C.F.R. § 401.109(d); *see Taransky*, 760 F.3d at 319 (noting that ALJ decisions do not have legal significance in future cases); *Christenson*, 2020 WL 3642315, at *5 ("ALJ decisions are not binding on another ALJ as only Council-level decisions can carry binding effect."). As applied here, any factual or legal findings in the ALJ decisions that granted Plaintiff's TTFT claims would not be binding in any other claim appeals.

To remove any doubt, the regulations re-affirm that only "[p]recedential decisions designated by the Chair of the Departmental Appeals Board in

accordance with § 401.109 of this chapter, are binding . . . ." 42 C.F.R. § 405.1063(c). Indeed, ALJ decisions are not even binding upon lower levels of administrative review, such as the QIC second level of review. *See* 42 C.F.R. § 405.968(b) (omitting ALJ decisions among the rulings that bind the QIC). As the Fourth Circuit notes, "[n]owhere does any policy or regulation suggest that the [Council] owes any deference at all to—much less is bound by—decisions of lower reviewing bodies addressing different disputes between different parties merely because they pertain to the same device." *Almy*, 679 F.3d at 310.

Furthermore, an ALJ's decision to depart from an LCD and approve coverage "applies only to the specific claim being considered and does not have precedential effect." 42 C.F.R. § 405.1062(b) (emphasis added); 70 Fed. Reg. 11420, 11458 (Mar. 8, 2005) ("[T]he ALJ or [Council] may decline to follow a policy in a particular case, but must explain the reason why the policy was not followed. These decisions apply only for purposes of the appeal in question, and do not have precedential effect."). In sum, the Medicare regulations unequivocally reject Plaintiff's assertion that a prior ALJ decision, which departed from the LCD and approved coverage, collaterally estops the Secretary from denying future claims for coverage.[10]

[10] ALJs are not bound by LCDs, but are required to afford them "substantial deference." 42 C.F.R. § 405.1062(a). ALJs are not authorized to "set aside or

Giving preclusive effect to ALJ decisions is also contrary to the Medicare statute, which provides that the Council must "review the case de novo." 42 U.S.C. § 1395ff(d)(2)(B) (emphasis added); *see Porzecanski v. Azar*, 943 F.3d 472, 477 (D.C. Cir. 2019) ("Because the review generally binds only the parties unless specifically designated as precedential, a favorable determination in one proceeding does not ensure that future claims will be approved.") (citing 42 C.F.R. §§ 401.109, 405.1130, 405.1048). If a favorable ALJ ruling collaterally estopped the Council from denying a beneficiary's claim for the same treatment, the Council could not perform a de novo review; instead, the Council would be bound to accept the ALJ's conclusions. The Third Circuit agrees, noting that "[a]lthough [the Council] is limited to considering only the record before it, its review of the ALJ's findings is *de novo* and [the Council] 'is not obligated to defer to the outcomes of prior decisions below.'" *Balko*, 555 F. App'x at 193 (citing *Almy*, 679 F.3d at 310 and section 1395ff(d)(2)(B)). Likewise, in *Taransky*, the Third Circuit rejected plaintiff's assertion that the Council's decision was "inconsistent with previous determinations by QICs and ALJs," holding that the Council "is free to depart from these lower agency rulings without concern, as only its decisions have legal significance." 760 F.3d at 319.

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review the validity of an . . . LCD for purposes of a claim appeal." *Id.* § 405.1062(c).

Because the Medicare regulations specifically designate ALJ decisions as non-binding and non-precedential, and the application of collateral estoppel is contrary to the Medicare statute, collateral estoppel does not apply. *See Astoria* at 111–12 (rejecting application of collateral estoppel to a federal statute because applying the principle would render a section of that statute superfluous); *Duvall*, 436 F.3d at 387-88.

2. Collateral estoppel on the basis of ALJ decisions would interfere with the discretion and deference afforded to the Secretary to implement the Medicare Statute.

If ALJ decisions were deemed binding, they would interfere with the deference and discretion afforded to the Secretary to implement the Medicare statute's "reasonable and necessary" standard for coverage of items and services furnished to program beneficiaries. "[T]he choice made between proceeding by general rule or by individual, *ad hoc* litigation is one that lies primarily in the informed discretion of the administrative agency." *SEC v. Chenery Corp.*, 332 U.S. 194, 203 (1947). The Medicare statute and regulations preserve "this discretion for the Secretary, leaving it to her judgment whether to proceed by implementing an NCD, by allowing regional contractors to adopt an LCD, or by deciding individual cases through the adjudicative process." *Almy*, 679 F.3d at 303. The Supreme Court has foreclosed arguments that interfere with this discretion, holding that "[t]he Secretary's decision as to whether a particular

medical service is 'reasonable and necessary' and the means by which she implements her decision, whether by promulgating a generally applicable rule or by allowing individual adjudication, are clearly discretionary decisions." *Heckler v. Ringer*, 466 U.S. 602, 617 (1984); *see also Guernsey Mem'l Hosp.*, 514 U.S. at 97 ("The Secretary's mode of determining benefits by both rulemaking and adjudication is, in our view, a proper exercise of her statutory mandate.").

As discussed at length above, nothing in the Medicare statute or regulations indicates that the Secretary intended for favorable ALJ decisions to be given preclusive effect in future cases. The Third Circuit notes "[n]owhere does any policy or regulation suggest that the [Council] owes any deference at all to—much less is bound by—decisions of lower reviewing bodies addressing different disputes between different parties." *Taransky*, 760 F.3d at 319 (quoting *Almy*, 679 F.3d at 310).[11] Likewise, in *Hynek v. Astrue*, the court concluded that a statute and regulation that "makes no mention of deference to a prior [ALJ] determination" implied that a favorable ruling should not be given preclusive effect. 2012 WL 460473, at *10 (D. Montana Feb. 13, 2012).

This is for good reason. The Medicare regulations designate ALJ decisions

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[11] Plaintiff's discussion of *de novo* review outside the Medicare context is irrelevant. Pl. Br. at 5. The issue here is not the standard for appellate review of a trial court's order applying collateral estoppel, but rather whether the application of collateral estoppel to ALJ decisions would frustrate the Council's statutory duty to review such decisions *de novo*.

as non-binding and non-precedential, which allows individual adjudication over Part B claims. Generally speaking, this inures to the benefit of Medicare beneficiaries, who, even after repeated denials of similar claims, have the right to de novo review of any subsequent claims. The application of collateral estoppel, therefore, is fundamentally inconsistent with individual adjudication of Part B claims. In Plaintiff's view, once a claim for benefits is approved, the Secretary would be estopped from ever denying a claim for the same treatment. Pl. Br. at 15-16. Individual adjudication would be impossible, because the Secretary could not review each claim appeal separately and approve or deny it on its own merits. Accordingly, it is within the Secretary's discretion *not* to be bound by ALJ rulings. *See generally Ringer*, 466 U.S. at 607-08 (distinguishing between ALJ and Council-level decisions that "applied only to the claimants involved in that case and [were] not to be cited as precedent in future cases" and a subsequent formal administrative ruling by the Secretary that bound ALJs and the Council); *Hunter v. Social Sec. Admin*, 808 F.3d 818, 822 (11th Cir. 2015) (noting that the deferential review afforded under section 405(g) means that "there is no inconsistency in finding that two successive ALJ decisions are supported by substantial evidence even when those decisions reach opposing conclusions."); *Almy*, 749 F.3d at 310 (concluding that plaintiff's "proposed expansion of what constitutes binding agency precedent would severely constrict the undisputed delegated authority of

the Secretary to administer the Medicare system.").

Here, the Secretary's decision that ALJ decisions are non-binding and non-precedential is expressed in the plain, unambiguous language of the applicable law and regulations. *See Avalon Place Trinity*, DAB No. 2819, at 13 (2017) ("An unappealed ALJ decision [does not set] a precedent binding on ALJs or the Board. When the *Board* has not reviewed the ALJ decision, the *Board* has not issued a decision in that case. Regardless of whether an ALJ decision was appealed to the Board, an ALJ decision is not precedential and does not bind the Board, and is relevant in later cases only to the extent its reasoning is on point and persuasive.") (italics in original), *aff'd*, *Avalon Place Trinity v. HHS*, 761 F. App'x 407 (5th Cir. Mar. 4, 2019). Because giving preclusive effect to ALJ rulings would contravene the Medicare regulations, the Court should decline to apply collateral estoppel here.

While Plaintiff fails to cite any cases on point,[12] the Third Circuit (see

[12] Plaintiff's reliance on the unpublished decision in *Brewster v. Barnhart*, 145 F. App'x 542 (6th Cir. 2005) is misplaced. Pl. Br. at 5. The court found that, under circumstances unique to Social Security disability appeals, an applicant (not the government) was bound by an ALJ's earlier finding concerning the exertion level of the applicant's past work. *Id.* at 546-48. Plaintiff's additional citation, Pl. Br. at 5, to a case concerning the unique circumstances of immigration appeals is similarly unhelpful. *Islam v. U.S. D.H.S.*, 136 F. Supp. 3d 1088 (N.D. Cal. 2015). Among other things, unlike the Medicare statute and regulations' prohibition on collateral estoppel here, the *Islam* court determined that the Immigration and Nationality Act permitted collateral estoppel of issues decided by an Immigration

Taranksy and *Balko*), as well as the Fourth, Fifth, Seventh, Ninth, and D.C. Circuits have each rejected similar attempts to bind federal agencies to non-precedential decisions in lower-level administrative appeals. In *Almy*, plaintiff asserted that Council decisions denying coverage for a medical device created a policy of denying treatment for that device. 679 F.3d at 299. The Fourth Circuit disagreed, noting that "[t]he Secretary's own regulations make clear that any policy implications in an adjudication do not have precedential effect. . . . The purported 'policy' in this case is nothing more than the accretion of individual decisions finding that the [device] does not meet the statutory requirements for coverage." *Id.* at 303 (citing 42 C.F.R. § 405.1062). The Fourth Circuit noted that Congress gave the Secretary discretion to "decide how to deal with hundreds of millions of Part B claims for coverage of thousands of devices every year." *Id.* at 304. Likewise, this Court should reject Plaintiff's attempt to elevate non-precedential ALJ opinions into binding coverage rules, which would "stultify the administrative process." *Id.* (quoting *Chenery*, 322 U.S. at 202).

The Fourth Circuit noted that other circuits have concluded that "[t]here is no authority for the proposition that a lower component of a government agency may bind the decision making of the highest level . . . [E]ven if these cases were

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Judge in granting asylum. *Id.* at 1093-94. Additionally, unlike here, the other elements of collateral estoppel were actually met in *Islam*. *Id.* at 1091-93.

found to evince internal inconsistency at a subordinate level, the [agency] itself would not be acting inconsistently." *Id.* at 310 (quoting *Community Care Found. v. Thompson*, 318 F.3d 219, 227 (D.C. Cir. 2003)). Along the same lines, the D.C. Circuit has emphasized its "well-established view that an agency is not bound by the actions of its staff if the agency has not endorsed those actions." *Comcast Corp. v. FCC*, 526 F.3d 763, 769 (D.C. Cir. 2008) (citing cases). Instead, "a definitive and binding statement on behalf of the agency must come from a source with the authority to bind the agency." *Devon Energy Corp. v. Kempthorne*, 551 F.3d 1030, 1040 (D.C. Cir. 2008). As applied in this context, the D.C. Circuit found that ALJ decisions are non-precedential and are not binding in subsequent claim determinations. *See Porzecanski*, 943 F.3d at 476, 485; *see also Freeman v. U.S. Dep't of the Interior*, 37 F. Supp. 3d 313, 344-45 (D.D.C. 2014) (finding that "unappealed" ALJ rulings could not estop the United States because such rulings were not binding on the agency or even on other ALJs and noting that the lack of appeal did not "elevate them to the level of a binding final agency action").

The Ninth Circuit explicitly adopted the reasoning in *Almy*, reversing a district court decision that "incorrectly measured agency inconsistency across" ALJ decisions. *Int'l Rehab. Sci. Inc. v. Sebelius*, 688 F.3d 994, 1001 (9th Cir. 2012); *see also County of Los Angeles v. Leavitt*, 521 F.3d 1073, 1079 (9th Cir. 2008) (noting that "intermediary interpretations are not binding on the Secretary,

who alone makes policy"). Likewise, the Seventh Circuit recognized that lower-level decisions may conflict and do not bind the Secretary. *Abraham Memorial Hosp. v. Sebelius*, 698 F.3d 536, 556 (7th Cir. 2012) ("The handful of prior Board decisions the Hospitals rely upon to purportedly show HHS's long-standing policy are not determinative. Our precedent instructs that Board decisions are not the decisions of the Secretary or her Administrator and are not authoritative."); *Homemakers North Shore, Inc. v. Bowen*, 832 F.2d 408, 413 (7th Cir. 1987) ("'The Secretary's position' is the position of the Department as an entity, and the fact that people in the chain of command have expressed divergent views does not diminish the effect of the agency's resolution of those disputes. An inconsistent administrative position means flipflops by the agency over time, rather than reversals within the bureaucratic pyramid."). The Fifth Circuit reached the same conclusion. *See Homan & Crimen, Inc. v. Harris*, 626 F.2d 1201, 1205 (5th Cir. 1980) ("[T]he decision of the [Provider Reimbursement Review Board] carries no more weight on review by the Secretary than any other interim decision made along the way in an agency where the ultimate decision of the agency is controlling.").

In sum, "Congress has delegated broad authority to the Secretary to determine when a device is reasonable and necessary, as well as broad authority to select the procedures used for making that determination. The decisions of local

contractors cannot deprive her of that discretion, *any more than the diverse decisions of district courts or courts of appeals throughout the country could bind the Supreme Court*." *Almy*, 679 F.3d at 311 (emphasis added). The doctrine of collateral estoppel cannot transform an ALJ ruling from what is – a decision by an intermediate-level tribunal that is only binding in a single case – to what it is not – an officially binding statement of policy by the Secretary. To do so would be contrary to the Medicare statute and regulations and would interfere with the discretion afforded to the Secretary. *See Christenson*, 2020 WL 3642315, at *6 ("In the administrative realm, it is not unreasonable or arbitrary for the Secretary to decide what stage deserves preclusive effect.").

B. The Elements of Collateral Estoppel are Not Met Here.

Even if ALJ decisions were capable of collateral estoppel effect the elements of collateral estoppel are not present here. The Third Circuit has identified four required elements for the application of collateral estoppel: "(1) the identical issue was previously adjudicated; (2) the issue was actually litigated; (3) the previous determination was necessary to the decision; and (4) the party being precluded from relitigating the issue was fully represented in the prior action." *Jean Alexander Cosmetics, Inc. v. L'Oreal USA, Inc.*, 458 F.3d 244, 249 (3d Cir. 2006) (internal quotations omitted). The Third Circuit considers whether the party being precluded "had a full and fair opportunity to litigate the issue in question in the

prior action, . . . and whether the issue was determined by a final and valid judgment." *Id.* (internal quotation marks and citations omitted). Third Circuit courts also require that the adjudicator at the prior proceeding confronted and decided the question, not merely remarked on it in dicta. *See Khalil v. Rohm & Haas Co.*, 2008 WL 383322, at *14 (E.D. Pa. Feb. 11, 2008) (citing *Hawksbill Sea Turtle v. Fed. Emergency Mgmt. Agency*, 126 F.3d 461, 465 (3d Cir. 1997)). Collateral estoppel generally will not apply when "'controlling facts or legal principles have changed significantly since the [prior] judgment.'" *Karns v. Shanahan*, 879 F.3d 504, 514 (3d Cir. 2018) (alteration in original) (quoting *Montana*, *Montana v. United States*, 440 U.S. 147, 155 (1979)).

First, the identical issue was neither previously adjudicated nor actually litigated in Plaintiff's claim appeals. The sole issue presently on appeal is whether Medicare coverage exists for Plaintiff's TTFT claims from December 2017 - February 2018. That issue was never litigated in Plaintiff's November 7, 2018 favorable ruling, which only concerned Plaintiff's TTFT claims from September - November 2017. Indeed, Plaintiff's favorable ruling merely concluded that the treatment "provided *on the dates of service* meet Medicare coverage criteria." AR at 3191 (emphasis added). The ALJ recognized that he was only authorized to decline to follow the LCD for the "particular case" before him. *Id.* at 3190. Because the favorable ruling was expressly limited to a particular time period, and

expressed no opinion about whether coverage might exist for other dates of service, there is no identity of issues between these claim appeals.

Indeed, Plaintiff's choice to file claim appeals meant that any favorable ALJ decision would not have preclusive effect in subsequent cases. If Plaintiff was concerned about re-litigating whether TTFT is a covered Medicare benefit, she could have challenged the LCD or petitioned CMS for a National Coverage Determination under entirely separate channels of review. *See* 42 U.S.C. § 1395y(l) (describing the process of requesting an NCD); 42 C.F.R. § 426.425 (only by raising an LCD challenge can an aggrieved party "state why the LCD is not valid"). Instead, Plaintiff chose to seek the limited relief available in a claim appeal and "cannot circumvent" the "distinct path provided for beneficiaries to secure broader coverage determinations" by asserting that a successful claim appeal has the same broad and binding effect as a local or national coverage determination. *Porzecanski*, 943 F.3d at 486, 486 n.12.

Second, the controlling facts and legal principles changed significantly in the time after Plaintiff's November 7, 2018 favorable claim appeal was decided. The January 18, 2019 unfavorable decision identified recent evidence that Plaintiff's GBM was not newly-diagnosed,[13] but rather that there was recurrence and/or

[13] On the other hand, the November 7, 2018 favorable ruling found that Plaintiff's GBM was newly-diagnosed. AR at 3190.

progression. AR at 2577. The ALJ found that "TTFT continued to be used as maintenance therapy during the dates of service at issue without evidence of other treatment options having been trialed, as suggested by the manufacturer and the [National Comprehensive Cancer Network]." *Id.* The ALJ also noted that the pending LCD reconsideration would alter coverage for newly-diagnosed GBM, but would not result in coverage for recurrent GBM. *Id.* Because the ALJ concluded that Plaintiff had developed recurrent GBM, and it is undisputed that TTFT for recurrent GBM is not covered by Medicare, changed circumstances in the facts and law prevent the application of collateral estoppel.

C. It Would be Unfair to Apply Collateral Estoppel Offensively Against the Secretary.

The Supreme Court has granted district courts "broad discretion" to determine when a plaintiff who has met the requisites for the application of collateral estoppel may employ that doctrine offensively. *See Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 331 (1979). The Court explained:

> If a defendant in the first action is sued for small or nominal damages, he [or she] may have little incentive to defend vigorously, particularly if future suits are not foreseeable. . . . [If] the application of offensive estoppel would be unfair to a defendant, a trial judge should not allow the use of offensive collateral estoppel.

Id. at 330–31 (citations omitted). Under Third Circuit law, a "finding of fairness to the defendant is thus a necessary premise to the application of offensive collateral

estoppel." *Raytech Corp. v. White*, 54 F.3d 187, 195 (3d Cir. 1995). It is also "well-settled that the Government may not be estopped on the same terms as any other litigant." *Community Health Servs.*, 467 U.S. at 60.

In *United States v. Mendoza*, the Supreme Court recognized that "'the Government is not in a position identical to that of a private litigant,' both because of the geographic breadth of government litigation and also, most importantly, because of the nature of the issues the government litigates." 464 U.S. 154, 159 (1984) (quoting *INS v. Hibi*, 414 U.S. 5, 8 (1973) (per curiam)). The Court noted that the government is "party to a far greater number of cases on a nationwide basis than even the most litigious private entity." *Id.* The government is likely to be involved in lawsuits against different parties that involve the same legal issues – issues that are frequently of substantial public importance. *Id.* at 160. Accordingly, allowing non-mutual collateral estoppel "would substantially thwart the development of important questions of law by freezing the first final decision rendered on a particular legal issue." *Id.* Rather than receiving the benefit of several courts of appeal decisions, the Supreme Court could only review one final decision before granting certiorari. *Id.*

In addition, the Court approved of the Solicitor General's discretion when determining whether to appeal. Unlike a private litigant, the Solicitor General "considers a variety of factors, such as the limited resources of the government and

the crowded dockets of the courts, before authorizing an appeal." *Id.* at 161. The Court concluded that "[t]he conduct of government litigation in the courts of the United States is sufficiently different from the conduct of private civil litigation in those courts so that what might otherwise be economy interests underlying a broad application of collateral estoppel are outweighed by the constraints which peculiarly affect the government." *Id.* at 162-63.

The policy reasons against collaterally estopping the United States apply with particular force here.[14] The Secretary did not participate in any of Plaintiff's appeals. Indeed, as in *Parklane* and *Mendoza*, it would not be practicable for the Secretary to defend himself in thousands of ALJ appeals filed each year. *See Christenson*, 2020 WL 3642315, at *7 ("several thousand beneficiary appeals filed annually makes it virtually impossible for the Secretary to be represented at every ALJ-level hearing.").[15] If the Secretary does not affirmatively elect to participate or become a party in ALJ proceedings, the proceedings simply move forward without the Secretary's involvement, as they did here. 42 C.F.R. §§ 405.1010(a),

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[14] Although the *Mendoza* court noted that its concerns with collateral estoppel against the government "are for the most part inapplicable where mutuality is present," it did not consider the unique circumstances surrounding Medicare claim appeals. 464 U.S. at 163-64.

[15] *See* 82 Fed. Reg. 4974, 4976 (Jan. 17, 2017) (noting that there were 650,000 pending ALJ appeals as of September 2016); *see, e.g.*, *Am. Hosp. Assoc. v. Azar*, 14-cv-851, Dkt. No. 96 (Mar. 25, 2020 Status Report) (for FY 2018, over 575,000 ALJ appeals pending and over 60,000 ALJ appeals received).

405.1012(b).

Nor would the Secretary have reason to believe that a favorable ALJ ruling could have preclusive effect in future claims, because that outcome would be contrary to the Medicare statute and regulations, Supreme Court precedent, and a number of circuit-level decisions. *See supra* §§ IV.B.1-2. The Medicare appeals process explicitly permits ALJs to reach varying conclusions, and gives the Council discretion to impose uniformity by issuing precedential decisions. As with federal courts, allowing conflicting decisions to percolate up to a higher level improves the decision-making process. *See Mendoza*, 464 U.S. at 160. Finding that an ALJ decision deprives the Secretary of discretion when to make a final determination would be akin to finding that a district court decision could bind the Supreme Court. *See Almy*, 679 F.3d at 310.

The Medicare appeals process is particularly unsuited to the application of collateral estoppel. In *Porzecanski*, the D.C. Circuit held that "stretch[ing] the outcome of a single claim dispute to foreclose a contrary decision in any future determination . . . is at odds with the Medicare regime. . . . Medical science changes. An accepted practice may be obsolete in a few years. Ordering HHS to cover [plaintiff's] treatments indefinitely can hardly be necessary to effectuate the district court's judgment regarding one treatment at a particular point in time." 943 F.3d at 486. Along similar lines, the Fourth Circuit wrote:

> [Plaintiff] seeks to impose massive resource costs on the Secretary, requiring her to reverse any decision at a lower level of adjudication either through promulgation of an NCD or through [Council] review lest that lower decision become precedent that precludes a different considered result in future cases before the [Council]. As the Secretary notes, there were 970 million Medicare Part B claims in 2008 alone, and the Secretary rarely participates in the lower level adjudications of those claim determinations. . . . The Secretary has simply not seen fit to invoke her final authority in every case in which there is an argument over whether the evidence adequately supports a finding that a device was "reasonable and necessary."

Id. at 311 (citations omitted). Accordingly, even assuming that collateral estoppel were legally supportable – which it is not – as a matter of policy, the doctrine of collateral estoppel has no place in Medicare claims appeals and would impose massive costs upon this critical national program and undermine its mission to support the health of the tens of millions of Americans enrolled in Medicare.

The fairness element is also lacking because collateral estoppel could only run against the Secretary – not against the beneficiary. While denial of a beneficiary's claim has no effect on any future claim, under Plaintiff's proposal, a single claim approval would forever estop the Secretary from denying future claims. Contrary to decades of Supreme Court precedent, the United States would be *more* susceptible to collateral estoppel than would private litigants. Because the application of collateral estoppel would be fundamentally unfair to the Secretary, it should not be applied here.

D. Plaintiff's Irrelevant Evidence and Argument Outside of the Administrative Record Should be Excluded

The Court's decision in this claim appeal must be based *only* upon the administrative record before the ALJ at the time he rendered the decision on appeal. Plaintiff concedes that judicial review in this case is authorized by 42 U.S.C. § 405(g) (made applicable to the Secretary by 42 U.S.C. 1395ii), which says in the relevant part:

> As part of the [Secretary]'s answer the [Secretary] shall file a certified copy of the transcript of the record including the evidence upon which the finding and decision complained of are based. The court shall have power to enter, *upon the pleadings and transcript of the record*, a judgment affirming, modifying, or reversing the decision of the [Secretary], with or without remanding the cause for a rehearing.

(emphasis added); *see* First Amended Complaint [Dkt. No. 27] at ¶ 5, Pl. Br. at 13. The Supreme Court has held that evidence outside of the administrative record should not be considered. *SEC v. Chenery Corp.*, 318 U.S. 80, 87 (1943) ("[t]he grounds upon which an administrative order must be judged are those upon which the record discloses that its action was based."); *Fargnoli v. Massanari*, 247 F.3d 34, 44 n.7 (3d Cir. 2001) (applying *Chenery* in cases arising under section 405(g)). Furthermore, under Third Circuit law, evidence that was not before the ALJ at the time he rendered the decision on appeal must be excluded from the Court's consideration of this case:

> [E]vidence that was not before the ALJ cannot be used to argue

> that the ALJ's decision was not supported by substantial evidence. . . . No statutory provision authorizes the district court to make a decision on the substantial evidence standard based on the new and material evidence never presented to the ALJ. . . For purposes of judicial review, the "record" is "the evidence upon which the findings and decision complained of are based." 42 U.S.C. § 405(g) (Sentence Three). That is the information that was before the ALJ, the final administrative decisionmaker when the Appeals Council denies review.

Matthews v. Apfel, 239 F.3d 589, 593-94 (3d Cir. 2001).

Citing *Matthews v. Apfel*, this Court found that evidence submitted to the Appeals Council after the ALJ issued his decision was irrelevant. *See Sturges v. Colvin*, 2014 WL 1682021, at *4, *4 n.12 (M.D. Pa. Apr. 28, 2014) (Mariani, J.); *see also, e.g.*, *Johnson v. Berryhill*, 2018 WL 7813741, at *5 (E.D. Pa. Dec. 19, 2018) ("It is well established that evidence that was not before the ALJ cannot be considered by a district court in its determination of whether or not the ALJ's decision was supported by substantial evidence, even if it was submitted to the Appeals Council. The only evidence that may be considered in assessing whether substantial evidence supports the ALJ's decision is the administrative record at the time of the ALJ's decision.").[16]

[16] Plaintiff's assertion that a court may take judicial notice of the January 29, 2020 ALJ decision is contrary to this precedent. *See also Baker v. Barnhart*, 457 F.3d 882, 891 (8th Cir. 2006) (holding that the district court abused its discretion by taking judicial notice of evidence outside the administrative record); *Khut v. Astrue*, 2010 WL 545868, at *10 (N.D. Cal. Feb. 12, 2010) (declining to take judicial notice of a subsequent favorable decision). In addition, that ALJ decision

Plaintiff's unfavorable decision on appeal is dated January 18, 2019. The court should exclude her *subsequent* favorable decisions, dated June 4, 2019, September 13, 2019, and January 29, 2020. *See* Exs. D-F to Pl. Br.[17] Because the favorable decisions were issued months *after* the unfavorable decision, they were not part of the administrative record before the ALJ and must be excluded under section 405(g) and Third Circuit law. *See* AR at 3169 (ALJ Exhibit List).

The subsequent favorable decisions should also be excluded as irrelevant to Plaintiff's collateral estoppel argument. The Third Circuit has said that the pendency of an appeal does not prevent the offensive use of a decision for preclusive purposes. *See United States v. 5 Unlabeled Boxes*, 572 F.3d 169, 175 (3d Cir. 2009) ("the pendency of an appeal does not affect the potential for res judicata flowing from an otherwise-valid judgment."). By extension, Plaintiff cannot apply a later ALJ decision to collaterally estop an earlier-decided ALJ decision simply because that earlier case remains pending on appeal.[18]

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is not a "pleading" under section 405(g) – it is merely a summary judgment exhibit. *See* Pl. Br. at 12.

[17] Plaintiff's reliance on *Opoka v. INS*, 94 F3d 392 (7th Cir. 1996) is also misplaced, because that immigration case did not arise under section 405(g). Pl. Br. at 13-14.

[18] Plaintiff cites no case holding that her subsequent favorable decisions can somehow estop the earlier ALJ decision presently on appeal. Pl. Br at 3. To the contrary, collateral estoppel requires that an issue was "previously adjudicated." *Jean Alexander*, 458 F.3d at 249. A subsequent decision simply cannot "previously adjudicate" an issue. Moreover, Plaintiff's cited cases are inapposite, as they concern concurrent trial court-level litigation.

VI. CONCLUSION

For the foregoing reasons, the Secretary respectfully requests that the Court grant his cross-motion for summary judgment and deny Plaintiff's motion for summary judgment.

Respectfully submitted,

DAVID J. FREED
United States Attorney

/s/ Eric S. Wolfish
ERIC S. WOLFISH
Special Assistant United States Attorney
United States Department of Health and Human Services
Office of the General Counsel, Region III
801 Market Street, Suite 9700
Philadelphia, PA 19107-3134
Email: eric.wolfish@hhs.gov
Phone: (215) 861-4511
Fax: (215) 861-4462

/s/ Navin Jani
NAVIN JANI
Assistant U.S. Attorney
228 Walnut Street
Suite 220
Harrisburg, PA 17108
(717) 221-4482
(717) 221-2246 (Facsimile)
navin.jani@usdoj.gov

Dated: August 28, 2020

CERTIFICATION BY COUNSEL PURSUANT TO LOCAL RULE 7.8(b)(2)

I, Eric S. Wolfish, hereby certify that this brief, exclusive of the Table of Contents, Table of Authorities, and Signature Block, is less than 35 pages pursuant to the Order dated August 25, 2020.

/s/ Eric S. Wolfish
ERIC S. WOLFISH
Special Assistant United States Attorney

Dated: August 28, 2020

CERTIFICATE OF SERVICE

I hereby certify that on this date, a true and correct copy of the foregoing Memorandum of Law in Support of the Secretary's Cross-Motion for Summary Judgment and in Opposition to Plaintiff's Motion for Summary Judgment was filed and served upon all counsel of record through the Court's CM/ECF system.

/s/ Eric S. Wolfish
ERIC S. WOLFISH
Special Assistant United States Attorney

Dated: August 28, 2020

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ROBERT TOWNSEND, Plaintiff, v. ALEX AZAR, in his official capacity as Secretary of the United States Department of Health and Human Services, Defendant.	Case No. 20 Civ. 1210 (ALC)

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT'S
MOTION FOR SUMMARY JUDGMENT

AUDREY STRAUSS
Acting United States Attorney for the
Southern District of New York
Counsel for Defendant
86 Chambers Street, Third Floor
New York, New York 10007
Telephone: (212) 637-3274
rachael.doud@usdoj.gov

Of Counsel:

RACHAEL DOUD
Assistant United States Attorney

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Defendant Alex M. Azar, II, Secretary of the United States Department of Health and Human Services (the "Secretary"), respectfully submits this memorandum of law in support of his motion for summary judgment.

PRELIMINARY STATEMENT

Plaintiff Robert Townsend ("Plaintiff") suffers from glioblastoma multiforme ("GBM"), an incurable form of brain cancer. This case arises from an Administrative Law Judge's ("ALJ's") denial of Plaintiff's claim for Medicare coverage of certain months of tumor treatment field therapy ("TTFT"), which may be used to treat GBM. On appeal, Plaintiff argues that the Secretary is collaterally estopped from denying the TTFT claim at issue, and any other claim that may arise in the future, because certain prior ALJ decisions allowed coverage for other months of TTFT claims. Plaintiff's claim fails.

First, Plaintiff lacks standing because he fails to establish an injury in fact. While denying coverage for Plaintiff's TTFT in the decision Plaintiff challenges, the ALJ concluded that Plaintiff would not be liable for the payment, which must instead be covered by the device manufacturer. Accordingly, the challenged decision did not result in any harm to Plaintiff.

Second, the doctrine of collateral estoppel does not apply to Medicare claims appeals such as this one. In arguing that non-precedential decisions of ALJs forever estop the Secretary from denying claims for TTFT treatment, Plaintiff relies on *Astoria Federal Savings and Loan Association v. Solimino*, 501 U.S. 104 (1991), which held that administrative decisions can have preclusive effect only where not inconsistent with Congress's intent in enacting the statute at issue. *Id.* at 108. Here, collateral estoppel is foreclosed by the Medicare statute and its implementing regulations, which make clear that ALJ decisions do not have preclusive effect. Every circuit to decide the issue has rejected similar attempts to bind federal agencies to non-precedential decisions

in administrative appeals; Plaintiff, meanwhile, fails to cite a single decision supporting his contrary view.

Even if there were no bar to collateral estoppel, moreover, Plaintiff would not be entitled to collateral estoppel in this case because the required elements are not met. It would also be unfair to apply collateral estoppel to the Secretary in this case because the Secretary had no reason to believe that failing to litigate the favorable ALJ decisions in this case would result in permanent collateral estoppel on the issue. Finally, even if collateral estoppel did apply to the ALJ decision at issue, it could not apply prospectively because controlling facts have changed significantly.

For the foregoing reasons, the Secretary respectfully requests that summary judgment be granted in his favor.

BACKGROUND

A. Statutory and Regulatory Framework

1. "Reasonable and Necessary" Medical Expenses

Medicare is a federal health insurance program for people who are elderly or have disabilities. *See* 42 U.S.C. § 1395 *et seq*. For a medical service to be covered by Medicare, it must fit within a benefit category established by the Medicare statute. *Id*.

This case concerns Medicare Part B, which extends coverage to certain types of durable medical equipment ("DME") for qualified recipients. 42 U.S.C. §§ 1395k(a), 1395x(s)(6). The various benefit categories available under Medicare Part B are set forth in 42 C.F.R. part 414. Almost all Medicare coverage determinations, including those in this case, are subject to 42 U.S.C. § 1395y(a)(1)(A), which excludes certain items from coverage. Under that section, "no payment may be made under . . . part B for any expenses incurred for items or services[] which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the

functioning of a malformed body member . . . ." 42 U.S.C. § 1395y. Unless there is an exception, this bar applies "[n]othwithstanding any other provision" of the Medicare statute. *Id.* § 1395y(a)(1)(A). The Centers for Medicare & Medicaid Services ("CMS"), which administers the Medicare program for the Secretary, has historically interpreted "reasonable and necessary" to mean that an item or service must be safe and effective, medically necessary and appropriate, and not experimental in order to qualify for reimbursement. *See* Medicare Program Integrity Manual ("MPIM") § 13.5.4.[1]

The Secretary has broad discretion in administering the "reasonable and necessary" standard. *See Heckler v. Ringer*, 466 U.S. 602, 617 (1984) (citing 42 U.S.C. § 1395ff(a)). The Secretary may choose to articulate "reasonable and necessary" standards through formal regulations that have the force and effect of law throughout the administrative process. *See* 42 U.S.C. §§ 1395hh; 1395ff(a)(1). The Secretary may also choose to issue National Coverage Determinations ("NCDs") "with respect to whether or not a particular item or service is covered nationally." 42 U.S.C. § 1395ff(f)(1)(B); *see also* 42 C.F.R. §§ 400.202, 405.1060. However, the Secretary is not required to promulgate regulations or policies that, "either by default rule or by specification, address every conceivable question" that may arise, *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 96 (1995), and may instead choose to proceed based on individual determinations. *See Heckler*, 466 U.S. at 617.

[1] The current MPIM is available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf. The MPIM "is a compilation of guidelines which CMS issues to instruct Medicare contractors on how to conduct medical review of Medicare claims submitted by Medicare providers and suppliers for payment." *Erringer v. Thompson*, 371 F.3d 625, 628 (9th Cir. 2004).

2. Enforcement of the "Reasonable and Necessary" Standard Through Local Coverage Determinations

Here, the Secretary has delegated to CMS broad authority to determine whether Medicare covers particular medical services. CMS, in turn, contracts with Medicare Administrative Contractors ("MACs"), such as Noridian Healthcare Solutions in this case, to administer certain day-to-day functions of the Medicare program. 42 U.S.C. § 1395kk-1. Consistent with controlling regulations and any applicable NCDs, an MAC makes coverage determinations, issues payments, and develops Local Coverage Determinations ("LCDs") for the geographic area it serves, *see* 42 U.S.C. § 1395ff(f)(2)(B), in accordance with the reasonable and necessary provisions in 42 U.S.C. § 1395y(a)(1)(A). *See* 42 U.S.C. §§ 1395kk-1(a)(4), 1395ff(f)(2)(B). An LCD is binding only on the contractor that issued it, and only at the initial stages of the Medicare claim review process, as opposed to later stages if a claimant should appeal a determination by a MAC. 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II). ALJs are not bound by LCDs, but are required to give them "substantial deference." 42 C.F.R. § 405.1062(a). If an ALJ declines to follow an LCD in a particular case, it "must explain the reasons why the policy was not followed." *Id.* § 405.1062(b). An ALJ's decision not to follow an LCD "applies only to the specific claim being considered and does not have precedential effect." *Id.*

In developing LCDs, MACs follow guidance contained in the MPIM. The MPIM requires MACs to publish LCDs that specify when "an item or service [is considered] to be reasonable and necessary." MPIM § 13.5.4. MACs develop LCDs by considering medical literature, the advice of local medical societies and medical consultants, public comments, and comments from the provider community. MPIM §§ 13.2.3, 13.5.2.1-3, .5; 66 Fed. Reg. 58,788 (Nov. 23, 2001). MACs also follow detailed procedures for issuing new or substantively revised LCDs, including

engaging in a notice-and-comment period, soliciting feedback and recommendations from the medical community, and presenting the policy in meetings of stakeholders. MPIM § 13.2.1.

3. The LCDs for TTFT Devices

In April 2011, the United States Food and Drug Administration approved the commercial distribution of a TTFT device manufactured by Novocure, Inc., and later rebranded Optune, for the treatment of recurrent GBM. (Certified Admin. Record ("CAR") 68, 149.) Following a review of the clinical literature, in October 2015, the DME MACs issued the original LCD for TTFT, indicating that TTFT was not covered for beneficiaries with GBM.[2] (CAR 149.) Another LCD that went into effect on January 1, 2017, remained substantively unchanged and stated that "Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary." (CAR 14-15.)

On August 7, 2018, the DME MACs received a request from Novocure for reconsideration of the TTFT LCD, noting that it did not address newly diagnosed GBM. (CAR 69.) Effective September 1, 2019, the LCD was revised to permit coverage for newly diagnosed GBM and continued coverage for newly diagnosed GBM beyond the first three months of therapy in certain circumstances. *See* CMS, Tumor Treatment Field Therapy (TTFT), Policy Article (A52711), 09/01/2019, available at https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52711&ver=16&Date=10%2f25%2f2019&DocID=A52711&bc=hAAAABAAAAAA& (last visited June 26, 2020). Novocure was "extremely pleased" with the 2019 LCD and noted that its coverage criteria "is generally similar to Optune's commercial coverage criteria

[2] The MPIM in effect at the time the original LCD was issued is available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R473PI.pdf (Transmittal 473, dated 6/21/2013).

for newly diagnosed GBM." *See.* Medicare Releases Final Local Coverage Determination Providing Coverage of Optune® for Newly Diagnosed Glioblastoma, https://www.novocure.com/medicare-releases-final-local-coverage-determination-providing-coverage-of-optune-for-newly-diagnosed-glioblastoma/ (last visited June 26, 2020).

4. Claims and Administrative Appeals

In order for a beneficiary to challenge the denial of a claim under the Medicare statute, he or she must submit a claim for payment to the Medicare contractor. *See generally* 42 U.S.C. § 1395y(a); 42 C.F.R. § 405.904. If the claim is denied, the beneficiary must generally exhaust the following four levels of administrative review before filing suit in district court. *Id.* First, the beneficiary may seek a redetermination from the Medicare contractor, which must be performed by a person who did not make the initial decision. 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. §§ 405.920, 405.940. At the second level, a beneficiary may seek reconsideration by a qualified independent contractor ("QIC") whose panel members must have "sufficient medical, legal, and other expertise, including knowledge of the Medicare program." 42 U.S.C. § 1395ff(b)(1)(A), 1395ff(c); 42 C.F.R. §§ 405.960, 405.968(c)(1). An LCD is not binding at this or higher levels of appeal. 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II); 42 C.F.R. § 405.968(b). At the third level, a beneficiary can request a hearing before an ALJ, who issues a decision based on the evidence presented at the hearing or otherwise admitted into the administrative record by the ALJ. 42 U.S.C. § 1395ff(b)(1)(A), 1395ff(d); 42 C.F.R. §§ 405.1000-02, 405.1042, 405.1046.

The administrative process ends in a review of the ALJ's decision by the Medicare Appeals Council (the "Council"), a division of the Departmental Appeals Board of the Department of Health and Human Services. 42 U.S.C. § 1395ff(b)(1)(A), (d)(2); 42 C.F.R. §§ 405.1100, 405.1122. The Council's decision (or the ALJ's decision, if not reviewed by the Council)

represents the final decision of the Secretary for purposes of administrative exhaustion. 42 U.S.C. § 1395ff(b)(1)(A), (d)(2)(A); 42 C.F.R. §§ 405.1048, 405.1130, 405.1136. If the Council does not render a decision within a specified timeframe, a beneficiary may request elevation to district court. 42 C.F.R. § 405.1132.

The claimant is entitled to judicial review of the Secretary's decision in the district court "as is provided in [42 U.S.C.] 405(g)." 42 U.S.C. § 1395ff(b)(1)(A). In such a review, the Secretary's findings of fact "if supported by substantial evidence, shall be conclusive." 42 U.S.C. § 405(g).

5. Advanced Beneficiary Notices

If Medicare coverage is denied to a beneficiary, Medicare will nevertheless pay the claim if neither the supplier nor the beneficiary knew or could reasonably have been expected to know that the item would not be covered. 42 U.S.C. § 1395pp; 42 C.F.R. § 411.400(a). The supplier can shift the risk of non-coverage to the beneficiary by providing him with advance written notice (called an "Advance Beneficiary Notice") of the specific reason why the item probably will not be covered. 42 C.F.R. § 411.404(b). Here, the ALJ found that there was no evidence in the record (such as Plaintiff having signed an Advance Beneficiary Notice) indicating that Plaintiff should have known that the device would not be covered, so he could not be financially responsible for the TTFT claims at issue. (*See* CAR 73.)

B. Plaintiff's Claims

Plaintiff, who has recurrent GBM, sought coverage of the Optune system supplied by Novocure for dates of service on August 7, 2018, September 7, 2018, and October 7, 2018. (CAR 67.) On August 13, 2018, September 13, 2018, and October 13, 2018, MAC Noridian Healthcare Solutions denied payment of the claims. (*Id.*) On January 3, 2019, Noridian issued a

redetermination affirming the initial denial of the claims. (*Id.*) Plaintiff requested reconsideration, and on March 19, 2019, the QIC determined that the device was not covered under Medicare. (*Id.*) The QIC found the supplier, Novocure, rather than Plaintiff, liable for the claims. (*Id.*)

On April 1, 2019, Plaintiff filed a request for an ALJ hearing. (CAR 67.) ALJ Brian Butler received evidence and held a hearing on May 29, 2019. (*Id.*) On June 25, 2019, ALJ Butler issued a decision denying Plaintiff's claims for Medicare coverage of the Optune system for the period at issue (ALJ Appeal No. 1-8429561876). (Compl., Dkt. 1, ¶ 22; CAR 67-74.) ALJ Butler noted that Plaintiff had recurrent GBM, having suffered a progression of the disease in 2018 after being initially diagnosed in 2011. (CAR 68.) ALJ Butler held that, while he was not bound by the LCD that categorically denied coverage for TTFT, he was required to give it substantial deference unless there was a particular reason to deviate from it. (CAR 71-72.) ALJ Butler concluded that deviation from the LCD was not warranted, including because Plaintiff had not been using the TTFT device at the recommended usage rate. (CAR 72.) ALJ Butler also found it significant that the new LCD that had then been proposed and later went into effect in September 2019 would provide coverage only for newly diagnosed GBM, and thus would not provide coverage for Plaintiff. (CAR 73.) While ALJ Butler denied coverage for TTFT for the dates at issue, he concluded that there was no evidence to suggest that Plaintiff knew, or should have been expected to know, that the device would not be covered, and that Plaintiff thus would not be responsible for payment. (*Id.*)

Following ALJ Butler's decision, Plaintiff appealed that decision to the Medicare Appeals Counsel. (CAR 19-23.) The Medicare Appeals Counsel did not issue a decision within 90 days, and Plaintiff elected to proceed to the district court. (CAR 1); *see* 42 C.F.R. 405.1016(f). This appeal is pursuant to 42 U.S.C. §§ 405(g) and 1395ff(b) (providing for judicial review as set forth in § 405(g)). (*See* Compl. ¶ 5.)

Plaintiff attempts to rely on coverage determinations issued by other ALJs pertaining to claims for other time periods, in which those ALJs chose to depart from the applicable LCD and found that Medicare coverage was available for those particular claims. Specifically, on November 8, 2018, ALJ David Krane ordered coverage for August through October 2017 (ALJ Appeal No. 1-7737575148). (CAR 29-43.) On February 4, 2019, ALJ Thomas Tyler ordered coverage for February 7, 2018 to April 7, 2018 (ALJ Appeal No. 1-8116629727). (CAR 51-57.) On August 15, 2019, ALJ Timothy Gates ordered coverage for November 2018 through January 2019 (ALJ Appeal No. 1-8637672132). (CAR 10-17.)[3] Plaintiff also cites a January 13, 2020, decision that is not in the administrative record, in which, Plaintiff says, ALJ Carolyn Jane Van Duzer ordered coverage for February through April 2019 (ALJ Appeal No. 3-8686737932). (*See* Dkt. No. 14 at 2.)

ARGUMENT

I. Standard of Review

Even though cross-motions for summary judgment are before the Court, the standard articulated in Federal Rule of Civil Procedure 56 is inapplicable because the Court has a more limited role in reviewing the administrative record. *See Murphy v. Sec'y of Health and Human Servs.*, 62 F. Supp. 2d 1104, 1106 (S.D.N.Y. 1999). Specifically, in an appeal arising under Section 405(g), the findings of the ALJ are conclusive unless not supported by substantial evidence or based on an incorrect legal standard. *Id*. Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Id.* (quoting *Richardson v.*

[3] These decisions were submitted by Plaintiff to the Medicare Appeals Counsel as part of his appeal, which was not ultimately heard because Plaintiff elected to proceed to district court without waiting for a decision.

Perales, 402 U.S. 389, 401 (1971)). The Court's review is limited to the administrative record. 42 U.S.C. §§ 405(g), 1395ff(b)(1)(A).

II. Plaintiff Lacks Standing

Standing requires that a plaintiff have "a personal stake in the outcome of the controversy [so] as to warrant his invocation of federal-court jurisdiction." *Warth v. Seldin*, 422 U.S. 490, 498 (1975). At its "irreducible constitutional minimum," this requires a plaintiff to demonstrate that it has "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016). To establish injury in fact, a plaintiff must show that it "suffered an invasion of a legally protected interest" that is "concrete and particularized" and "actual or imminent, not conjectural or hypothetical." *Id.* at 1548 (citation omitted).

Here, while ALJ Butler denied Medicare coverage for the time period at issue, he did not hold Plaintiff responsible for the amount owed, which must instead be paid by the device manufacturer. (CAR 73.) Because Plaintiff does not have to pay anything, he has not suffered an injury in fact that is "actual or imminent." *Spokeo*, 136 S. Ct. at 1548 ("[A] bare procedural violation, divorced from any concrete harm, [does not] satisfy the injury-in-fact requirement of Article III"); *see also Thole v. U.S. Bank N.A.*, 140 S. Ct. 1615, 1619-20 (2020) (plaintiffs did not have standing notwithstanding the fact that ERISA afforded them a cause of action to sue because they would receive the same payments whether they won or lost). Accordingly, Plaintiff lacks standing. This alone is dispositive of Plaintiff's case and warrants dismissal.

III. The Common Law Doctrine of Collateral Estoppel Is Inapplicable

Even if Plaintiff did not lack standing, Defendant would still be entitled to summary judgment because Plaintiff's central argument—that prior ALJ decisions estopped any denial of

coverage—fails. This is so for two reasons. First, collateral estoppel is inapplicable to administrative determinations in this context. Second, the elements of collateral estoppel have not been met.

A. Collateral Estoppel is Inapplicable to ALJ Decisions in Medicare Claim Appeals

In arguing that prior ALJ decisions should have preclusive effect, Plaintiff relies heavily on the Supreme Court's decision in *Astoria*, in which the Court indicated that collateral estoppel may, in some circumstances, be based on agency determinations when the agency is acting in a "judicial capacity." *Astoria*, 501 U.S. at 107-08; Dkt. No. 14 at 3; Compl. ¶¶ 1, 10. Plaintiff fails to acknowledge, however, that the Court in *Astoria* held that agency decisions should not be given preclusive effect when there is a contrary legislative intent and that, applying that principle, the agency decision at issue in that case had no preclusive effect. 501 U.S. at 106-108.[4] Here, likewise, the Medicare statute and regulations make clear that ALJ coverage determinations do not have preclusive effect.

1. *Federal Regulations Provide that ALJ Decisions Do Not Bind the Secretary in Future Cases*

As an initial matter, the Medicare statute and regulations make explicit that ALJ decisions are not meant to have preclusive effect. The Medicare regulations sharply distinguish between a narrow category of decisions that are intended to be precedential and thus binding on future administrative appeals and any other decisions, which are non-precedential and not binding. Specifically, in Medicare coverage cases, only Council-level decisions have the potential to become precedential, and even those decisions are precedential only if they are so designated by

[4] *United States v. Stauffer Chem. Co.*, 464 U.S. 165 (1984), the other case Plaintiff cites in his complaint, addressed the question of whether the government was collaterally estopped based on a prior *court* decision (there, a decision of the Tenth Circuit Court of Appeals). *Id.* at 170-74.

the Chair of the Departmental Appeals Board. 42 C.F.R. § 401.109. Council decisions designated as precedential must be made available to the public, with personally identifiable information removed, and notice of precedential decisions must be published in the Federal Register. 42 C.F.R. § 401.109(b). Those decisions are then given "precedential effect" and are binding on "all HHS components that adjudicate matters under the jurisdiction of CMS." *Id.* § 401.109(c). The term "precedential effect" means that the Council's:

> (1) Legal analysis and interpretation of a Medicare authority or provision is binding and must be followed in future determinations and appeals in which the same authority or provision applies and is still in effect; and
>
> (2) Factual findings are binding and must be applied to future determinations and appeals involving the same parties if the relevant facts are the same and evidence is presented that the underlying factual circumstances have not changed since the issuance of the precedential final decision.

Id. § 401.109(d). Accordingly, the term "precedential effect" is synonymous with a decision having binding or preclusive effect. *See Taransky v. Sec. U.S. Dep't of Health & Human Servs.*, 760 F.3d 307, 319 (3d Cir. 2014) (noting that the Medicare Appeals Council was free to depart from prior decisions of ALJs because only Appeals Council decisions "have legal significance"). It is undisputed that no Council decision, much less one designated as precedential, has been rendered with respect to Plaintiff's claims.

The regulations governing LCDs further support that ALJ decisions are nonbinding and collateral estoppel is therefore inapplicable. Specifically, Plaintiff's collateral estoppel argument relies upon favorable ALJ decisions that departed from the applicable LCD when approving TTFT treatment. But governing regulations explicitly provide that an ALJ's decision to depart from an LCD "applies only to the specific claim being considered and does not have precedential effect." 42 C.F.R. § 405.1062(b); 70 Fed. Reg. 11420, 11458 (Mar. 8, 2005) ("[T]he ALJ or [Council] may

decline to follow a policy in a particular case, but must explain the reason why the policy was not followed. These decisions apply only for purposes of the appeal in question, and do not have precedential effect."). These regulations reaffirm that only "[p]recedential decisions designated by the Chair of the Departmental Appeals Board in accordance with § 401.109 of this chapter, are binding . . . ." 42 C.F.R. § 405.1063(c). Indeed, ALJ decisions are not even binding on lower levels of administrative review, such as the QIC second level of review. *See* 42 C.F.R. § 405.968(b) (omitting ALJ decisions among the rulings that bind the QIC).

Giving preclusive effect to ALJ decisions is also contrary to the Medicare statute itself, which provides that the Council must "review the case de novo." 42 U.S.C. § 1395ff(d)(2)(B). If a favorable ALJ ruling collaterally estopped the Council from denying a beneficiary's claim for the same treatment, the Council could not perform a *de novo* review; instead, the Council would be bound to accept the ALJ's conclusions. *See Almy v. Sebelius*, 679 F.3d 297, 310 (4th Cir. 2012) (rejecting challenge to denial of Medicare Part B coverage for device, reasoning in part that the Council's obligation to undertake "de novo" review was "incompatible with [plaintiff's] proffered notion that the [Council] is somehow obligated to defer to the outcomes of prior decisions below").

This is in line with the guidance from The Restatement (Second) of Judgments § 83 (1982) that:

> (4) An adjudicative determination of an issue by an administrative tribunal does not preclude relitigation of that issue in another tribunal if according preclusive effect to determination of the issue would be incompatible with a legislative policy that:
>
> > (a) The determination of the tribunal adjudicating the issue is not to be accorded conclusive effect in subsequent proceedings; or
> >
> > (b) The tribunal in which the issue subsequently arises be free to make an independent determination of the issue in question.

Medicare regulations explicitly state that ALJ decisions are not to be accorded conclusive

effect as they are non-precedential, and the Council's *de novo* review means that it is free to make an independent determination. Accordingly, the Medicare statute and regulations bar the application of collateral estoppel to ALJ decisions.

2. *Applying Collateral Estoppel Would Interfere with the Discretion and Deference Afforded to the Secretary to Implement the Medicare Statute*

Deeming ALJ decisions binding on future coverage determinations would also run contrary to the deference and discretion afforded to the Secretary to implement the Medicare statute, particularly as pertains to the "reasonable and necessary" standard for coverage of items and services furnished to program beneficiaries.

"[T]he choice made between proceeding by general rule or by individual, ad hoc litigation is one that lies primarily in the informed discretion of the administrative agency." *SEC v. Chenery Corp.*, 332 U.S. 194, 203 (1947). Here, the Medicare statute and regulations preserve "this discretion for the Secretary, leaving it to her judgment whether to proceed by implementing an NCD, by allowing regional contractors to adopt an LCD, or by deciding individual cases through the adjudicative process." *Almy*, 679 F.3d at 303. The Supreme Court has foreclosed arguments that interfere with this discretion, holding that "[t]he Secretary's decision as to whether a particular medical service is 'reasonable and necessary' and the means by which she implements her decision, whether by promulgating a generally applicable rule or by allowing individual adjudication, are clearly discretionary decisions." *Ringer*, 466 U.S. at 617; *see also Guernsey Mem'l Hosp.*, 514 U.S. at 97 ("The Secretary's mode of determining benefits by both rulemaking and adjudication is, in our view, a proper exercise of her statutory mandate.").

As noted above, the Medicare regulations designate ALJ decisions as non-binding and non-precedential, which allows individual adjudication over Part B claims. This often inures to the

benefit of Medicare beneficiaries, who, even after repeated denials of similar claims, have the right to *de novo* review of any subsequent claims. The application of collateral estoppel would be fundamentally inconsistent with individual adjudication of Part B claims. In Plaintiff's view, once a claim for benefits is approved, the Secretary would be estopped from ever denying a claim for the same treatment. (Compl. ¶¶ 1-4; Dkt. No. 14 at 1, 3.) Individual adjudication would be impossible, because the earliest-in-time ALJ ruling would forever bind the Secretary. Accordingly, it is within the Secretary's discretion not to be bound by ALJ rulings. *See generally Ringer*, 466 U.S. at 607-08 (distinguishing between ALJ and Council-level decisions that "applied only to the claimants involved in that case and [were] not to be cited as precedent in future cases" and a subsequent formal administrative ruling by the Secretary that bound ALJs and the Council).

Here, the Secretary's decision that ALJ determinations are non-binding and non-precedential is expressed in the plain, unambiguous language of the applicable law and regulations. *See Avalon Place Trinity*, DAB No. 2819, at 13 (2017) ("[An] unappealed ALJ decision [does not set] a precedent binding on ALJs or the Board. When the Board has not reviewed the ALJ decision, the Board has not issued a decision in that case. Regardless of whether an ALJ decision was appealed to the Board, an ALJ decision is not precedential and does not bind the Board, and is relevant in later cases only to the extent its reasoning is on point and persuasive."), *aff'd*, *Avalon Place Trinity v. HHS*, 761 F. App'x 407 (5th Cir. Mar. 4, 2019). Because giving preclusive effect to ALJ rulings would contravene the Secretary's choice to proceed by individual determinations, the Court should decline to apply collateral estoppel here.

While Plaintiff fails to cite any cases on point,[5] the Third, Fourth, Fifth, Seventh, Ninth,

[5] Plaintiff's reliance on the unpublished decision in *Brewster v. Barnhart*, 145 F. App'x 542 (6th Cir. 2005) (Dkt. No. 14 at 3), is misplaced. There, the court found that, under circumstances

and D.C. Circuits have each rejected similar attempts to bind federal agencies to non-precedential decisions in lower-level administrative appeals. *See Taransky*, 760 F.3d at 319; *Almy*, 679 F.3d at 299-310; *Int'l Rehab. Sci. Inc. v. Sebelius*, 688 F.3d 994, 1001 (9th Cir. 2012) (reversing district court opinion that "incorrectly measured agency inconsistency across" ALJ decisions); *Abraham Lincoln Mem'l Hosp. v. Sebelius*, 698 F.3d 536, 556 (7th Cir. 2012) ("The handful of prior Board decisions the Hospitals rely upon to purportedly show HHS's long-standing policy are not determinative. Our precedent instructs that Board decisions are not the decisions of the Secretary or her Administrator and are not authoritative."); *Cmty. Care Found. v. Thompson*, 318 F.3d 219, 227 (D.C. Cir. 2003) ("There is no authority for the proposition that a lower component of a government agency may bind the decision making of the highest level."); *Homemakers North Shore, Inc. v. Bowen*, 832 F.2d 408, 413 (7th Cir. 1987) ("'The Secretary's position' is the position of the Department as an entity, and the fact that people in the chain of command have expressed divergent views does not diminish the effect of the agency's resolution of those disputes. An inconsistent administrative position means flip-flops by the agency over time, rather than reversals within the bureaucratic pyramid."); *Homan & Crimen, Inc. v. Harris*, 626 F.2d 1201, 1205 (5th Cir. 1980) ("[T]he decision of the [Provider Reimbursement Review Board] carries no more weight on review by the Secretary than any other interim decision made along the way in an agency where the ultimate decision of the agency is controlling.").

In *Almy*, the plaintiff challenged decisions of the Medicare Appeals Counsel denying coverage for a medical device, arguing that the decisions created a policy of denying treatment for that device and the Secretary should have implemented that policy prospectively. 679 F.3d at 299,

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unique to Social Security disability appeals, an applicant (not the government) was bound by an ALJ's earlier finding concerning the exertion level of the applicant's past work. *Id.* at 546-48.

303. The Fourth Circuit disagreed, noting that "[t]he Secretary's own regulations make clear that any policy implications in an adjudication do not have precedential effect . . . . The purported 'policy' in this case is nothing more than the accretion of individual decisions finding that the [device] does not meet the statutory requirements for coverage." *Id.* at 303 (citing 42 C.F.R. § 405.1062). The court noted that Congress gave the Secretary discretion to "decide how to deal with hundreds of millions of Part B claims for coverage of thousands of devices every year." *Id.* at 304. This Court should likewise reject Plaintiff's attempt to elevate non-precedential ALJ opinions to binding coverage rules, which would "stultify the administrative process." *Id.* (quoting *Chenery*, 332 U.S. at 202).

In *Almy*, the Court noted that other circuits have concluded that "[t]here is no authority for the proposition that a lower component of a government agency may bind the decision making of the highest level . . . [E]ven if these cases were found to evince internal inconsistency at a subordinate level, the [agency] itself would not be acting inconsistently." *Id.* at 310 (quoting *Comty. Care Found.*, 318 F.3d at 227). Along these same lines, the Third Circuit rejected the argument that the Medicare Appeals Council was bound by prior ALJ rulings recognizing "the validity of almost identical orders," explaining that "the Appeals Council is free to depart from these lower agency rulings without concern, as only its decisions have legal significance." *Taransky*, 760 F.3d at 319. Similarly, the D.C. Circuit has emphasized its "well-established view that an agency is not bound by the actions of its staff if the agency has not endorsed those actions." *Comcast Corp. v. FCC*, 526 F.3d 763, 769 (D.C. Cir. 2008) (citing cases). Instead, "a definitive and binding statement on behalf of the agency must come from a source with the authority to bind the agency." *Devon Energy Corp. v. Kempthorne,* 551 F.3d 1030, 1040 (D.C. Cir. 2008); *see also Freeman v. U.S. Dep't of the Interior*, 37 F. Supp. 3d 313, 344-45 (D.D.C. 2014) ("unappealed"

ALJ rulings could not estop the United States because such rulings were not binding on the agency and lack of appeal did not "elevate them to the level of a binding final agency action").

The Ninth Circuit explicitly adopted the reasoning in *Almy*, reversing a district court decision that "incorrectly measured agency inconsistency across" ALJ decisions. *Int'l Rehab. Sci. Inc.*, 688 F.3d at 1001; *see also Cnty. of Los Angeles v. Leavitt*, 521 F.3d 1073, 1079 (9th Cir. 2008) (noting that "intermediary interpretations are not binding on the Secretary, who alone makes policy"). The Fifth Circuit reached the same conclusion. *See Homan & Crimen, Inc.*, 626 F.2d at 1205 ("[T]he decision of the [Provider Reimbursement Review Board] carries no more weight on review by the Secretary than any other interim decision made along the way in an agency where the ultimate decision of the agency is controlling.").

In sum, "Congress has delegated broad authority to the Secretary to determine when a device is reasonable and necessary, as well as broad authority to select the procedures used for making that determination." *Almy*, 679 F.3d at 311. The doctrine of collateral estoppel cannot transform an ALJ ruling from a decision by an intermediate-level tribunal that is only binding in a single case to an officially binding statement of policy by the Secretary. To do so would be contrary to the Medicare statute and regulations.

3. *Collateral Estoppel Is Contrary to the Medicare Act's Presentment and Channeling Requirements*

Plaintiff's argument that the Secretary is collaterally estopped by favorable ALJ decisions as to future claims for TTFT is also contrary to the Medicare Act's presentment and channeling requirements.

In *Porzecanski v. Azar*, 943 F.3d 472 (D.C. Cir. 2019), the D.C. Circuit recently held that the Medicare statute prohibits a Medicare beneficiary from obtaining "prospective equitable relief

mandating that HHS recognize his treatment as a covered Medicare benefit in all future claim determinations." *Id.* at 475. The facts in *Porzecanksi* are similar to those in the instant case. Porzecanski suffered from a rare, life-threatening condition with no known cure and started on an experimental regimen of a biological product. *Id.* at 476. After one of his claims was denied at the ALJ level and the Council did not render a decision within the required time frame, the plaintiff filed in federal court. *Id.* at 477. While the federal case was pending, the plaintiff continued to submit monthly Medicare claims, which were approved by a QIC or ALJ. *Id*. On appeal of his denied claim, the plaintiff sought declaratory and injunctive relief confirming his entitlement to Medicare coverage for the product and requiring the Secretary to provide Medicare benefits. *Id.*

The D.C. Circuit held that the plaintiff could not "satisfy § 405(g)'s presentment requirement with respect to future claims because those claims have not yet arisen." *Id.* at 482. Because Medicare claims can only be filed after the medical service has been furnished, and Section 405(g) requires appeals from "decision[s]" of the Secretary, the presentment requirement could not be met: "[T]he Secretary has not decided [plaintiff's] future claims because—to state the obvious—none has been submitted." *Id.* The court thus rejected the plaintiff's request to preclude the Secretary from concluding that future claims were not covered by Medicare—the same relief that Plaintiff seeks here. *Id.* at 482 (finding plaintiff's "strained position" to be "at odds with Supreme Court precedent."). In support, the D.C. Circuit relied on two Supreme Court decisions: *Ringer* and *Illinois Council*. In *Ringer*, "the Court held that § 405(g) barred a patient from obtaining declaratory and injunctive relief compelling the Secretary to conclude that his future surgery was 'reasonable and necessary' under the Medicare Act." *Id.* (citing 466 U.S. at 620-21). Although the patient sought equitable relief, it was "essentially one requesting the payment of benefits," which constitutes a "claim arising under" the Medicare Act. *Id.* at 482-83 (quoting

Ringer, 466 U.S. at 620-21). Likewise, in *Shalala v. Illinois Council on Long Term Care*, 529 U.S. 1 (2000), the Court declared that a "claim for future benefits is a § 405(h) claim" and "all aspects" of any future claim "must be channeled through the administrative process." *Id.* (citing *Illinois* Counsel, 529 U.S. at 12). The D.C. Circuit thus concluded, "*Ringer* and *Illinois Council* directly foreclose [plaintiff's] attempt to recast the requested relief as anything other than a claim for future benefits." *Id*. Likewise, Plaintiff's assertion that the Secretary is estopped from denying his future claims for TTFT treatment "runs headlong into the Supreme Court's instruction that 'all aspects' of a claim be first channeled through the agency." *Id.* (quoting *Illinois Council*, 529 U.S. at 12). Plaintiff cannot leverage a favorable ALJ decision to estop the Secretary from denying "future claims for the same reasons." *Id.* at 483-84.

B. The Elements of Collateral Estoppel Are Not Met

"A party seeking to invoke collateral estoppel must establish that (1) the identical issue was raised in a previous proceeding; (2) the issue was actually litigated and decided in the previous proceeding; (3) the party had a full and fair opportunity to litigate the issue; and (4) the resolution of the issue was necessary to support a valid and final judgment on the merits." *In re Snyder*, 939 F.3d 92, 100 (2d Cir. 2019). Plaintiff cannot meet that standard here.

Plaintiff attempts to point to two earlier ALJ decisions—ALJ Appeal No. 1-7737575148 and ALJ Appeal No. 1-8116629727—as supposedly estopping the denial of the claims at issue. (*See* Compl. ¶ 21 (citing ALJ Appeal No. 1-8116629727); Dkt. No. 14 at 2 (citing ALJ Appeal No. 1-7737575148).) Those decisions did not involve the identical issue as in this case, however, because each decision was limited to coverage for a specific period of time.[6] Specifically, ALJ

[6] While Plaintiff also attempts to rely on ALJ decisions issued *after* the one challenged in this case (*see* Dkt. No. 14 at 2), collateral estoppel can only be based on a prior decision. *See In re Snyder*,

Appeal No. 1-7737575148 involved a coverage determination for August through October 2017 and ALJ Appeal No. 1-8116629727 involved a coverage determination for February 7, 2018 to April 7, 2018, while the ALJ decision challenged here involved a coverage determination for August through October 2018. Each decision specified that it pertained only to the coverage period at issue. (*See* CAR 43, 51, 68.) The issues raised in the different appeals also are not identical because each appeal involved its own submission of evidence and hearing, and the facts relevant to the determinations—for example the LCDs in effect at the time and the medical literature—evolve over time. (*See generally* CAR 143 (Plaintiff's attorney noting that "medicine and science progress").) For example, as ALJ Butler noted, at the point he issued his decision the LCD that would later provide coverage for newly-diagnosed GBM, but not recurrent GBM, had been proposed—a fact ALJ Butler found significant. (CAR 73.) Because each ALJ appeal did not address the same issue, collateral estoppel does not apply. *See, e.g.*, *Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 435 F.3d 1356, 1361-62 (Fed. Cir. 2006) (declining to apply collateral estoppel where patent infringement involved two distinct time periods). Collateral estoppel is also inapplicable because, for the same reasons, the same issue was not actually litigated. *See Interoceanica Corp. v. Sound Pilots, Inc.*, 107 F.3d 86, 91-92 (2d Cir. 1997) (finding issue not actually litigated or decided where prior decision explicitly stated it did not reach an issue); *see also California Cmtys. Against Toxics v. EPA*, 928 F.3d 1041, 1052 (D.C. Cir. 2019) (finding issues not actually litigated where court stated it "need not address" the issue).

The third element of collateral estoppel also is not met because the Secretary's opportunity

939 F.3d at 100 (issue must have been raised, litigated and decided in a "previous proceeding"). At any rate, the subsequent decisions Plaintiff cites also pertained to different time periods from that at issue, so would not have collateral estoppel effect even if issued before the decision challenged here.

to litigate is limited in Medicare coverage appeals. The Secretary cannot participate in the first two levels of the administrative appeals process. *See* 42 C.F.R. §§ 405.948, 405.968. *See Genesis Health Ventures, Inc. v. Sebelius*, 798 F. Supp. 2d 170, 182 (D.D.C. 2011) ("[I]f an intermediary finds coverage and pays a claim, there is never an administrative appeal, and the Secretary would have no knowledge of the intermediary's decision nor opportunity to review those actions."). The Secretary's participation is also limited in ALJ appeals. When a beneficiary is unrepresented, the Secretary cannot be a party to the hearing. 42 C.F.R. § 405.1012(a). If the Secretary does not affirmatively elect to participate or become a party in ALJ proceedings, the proceedings move forward without the Secretary's involvement. 42 C.F.R. §§ 405.1010(a), 405.1012(b). Although the Secretary may participate or become a party in ALJ hearings involving beneficiaries represented by counsel, it is impracticable for the Secretary to litigate thousands of Medicare claim appeals filed each year at the ALJ level. 42 C.F.R. §§ 405.1010(a), 405.1012(a). *See* U.S. Government Accountability Office Report at 1, 12 (May 2016), https://www.gao.gov /assets/680/677034.pdf (last visited April 17, 2020); *see also* 82 Fed. Reg. 4974, 4976 (Jan. 17, 2017) (noting that there were 650,000 pending ALJ appeals as of September 2016); *Am. Hosp. Assoc. v. Azar*, 14-cv-851, Dkt. No. 96 (Mar. 25, 2020 Status Report) (for FY 2018, over 575,000 ALJ appeals pending and over 60,000 ALJ appeals received). If the Secretary does not become a party to an ALJ hearing, he cannot appeal a favorable ruling to the Council. 42 C.F.R. §§ 405.1012, 405.1102(a)(1), (d). In other words, the Secretary would need to litigate every ALJ hearing in order to have the right to appeal any decisions favorable to the beneficiary. Accordingly, because the Secretary's opportunity to appeal was extremely limited, there was not a full and fair opportunity to litigate.

Finally, even if the Court were to conclude that Plaintiff has established the required

elements, courts have recognized an exception to preclusion even where all the elements for estoppel are met. Specifically, where there is an incentive against litigating smaller matters because the cost outweighs the significance of the issue, it is unfair to allow the decisions in those smaller matters to have large preclusive effects. *See Power Integrations v. Semiconductor Components Indus.*, 926 F.3d 1306, 1312, 1313 (Fed. Cir. 2019) (holding that the exception of "a lack of opportunity or incentive to litigate the first action" prevented preclusion where there was a disparity in incentives to appeal an issue); *Rawls v. Daughters of Charity of St. Vincent De Paul, Inc.*, 491 F.2d 141, 148 (5th Cir. 1974) (no preclusive effect given to habeas corpus hearing finding involuntary hospitalization was illegal in subsequent suit against hospital for false imprisonment because the hospital "had far less incentive to contest the unlawfulness of the plaintiff's detention than at present"). Such is the case here, where the Secretary's involvement in the litigation of every claim would be an inefficient use of resources better put towards the Medicare program. Unreviewed and non-precedential ALJ decisions should not be given preclusive effect, which would result in great cost to Medicare.

C. Even If Collateral Estoppel Applied, It Would Have No Further Force After the New LCD Became Effective on September 1, 2019

Even if collateral estoppel applied here, it would have no force after the new LCD became effective on September 1, 2019. Collateral estoppel generally will not apply when "controlling facts or legal principles have changed significantly since the [prior] judgment." *Montana v. United States*, 440 U.S. 147, 155 (1979). Here, there was a significant change between the old LCD, which categorically denied coverage for TTFT treatment, and the new LCD, which allows coverage of TTFT under certain circumstances. Accordingly, if Plaintiff was to prevail on collateral estoppel, only the ALJ decision challenged in this case would be affected. Further

preclusive or injunctive relief would not be warranted, because the new LCD has already been in place for over nine months.

Similarly, the medical context of this case necessarily means that the controlling facts are constantly changing. Physicians do not prescribe treatment, no matter how potentially effective, indefinitely into the future. A treatment that may have been beneficial for a patient at one point in time could be ineffective or dangerous if continued (for example, when a patient suffers serious side effects). In this case, there is no evidence that the facts supporting Plaintiff's claim for coverage for August through October 2018 will continue indefinitely into the future. Even if Plaintiff's medical history remained unchanged for two years, it would be pure speculation to assert that the facts would remain unchanged for any claim Plaintiff might file in the future.

IV. To the Extent Plaintiff Makes Any Other Arguments for Reversal in His Motion, Those Arguments Fail

It appears that Plaintiff intends in his motion for summary judgment to raise the sole argument that ALJ Butler was barred by collateral estoppel from denying coverage for the period at issue. (*See* Dkt. No. 14.) If Plaintiff's motion is limited to that argument, any other arguments are waived. *See Graves v. Finch Pruyn & Co.*, 457 F.3d 181, 184 (2d Cir. 2006) (arguments not raised on appeal are waived).

In any event, even if Plaintiff's motion does raise the other arguments referenced in the complaint, those arguments fail. Plaintiff's sole claim under 42 U.S.C. § 405(g) is that ALJ Butler's decision was contrary to law (Compl. Count I)—presumably based on the erroneous argument, addressed above, that it was barred by collateral estoppel. The remainder of the claims in Plaintiff's complaint are asserted under the Administrative Procedure Act ("APA"). (*See* Compl. Counts II-VI.) The APA does not apply here, however, because this appeal is pursuant to

42 U.S.C. § 1395ff(b), which permits judicial review in accordance with 42 U.S.C. § 405(g). Section 405(g), in turn, provides for review under the substantial evidence standard—not any other standard that may be provided for by the APA. *See Pierce v. Leavitt*, No. 05-36176, 2007 WL 2193761, at *1 (9th Cir. Aug. 1, 2007) (rejecting plaintiff's assertion that APA "arbitrary and capricious" standard applies to Section 405(g) cases); *Estate of Morris v. Shalala*, 207 F.3d 744, 745 (5th Cir. 2000) (concluding that Section 405(g) cases are not governed by the APA standard of review); *Diapulse Corp. v. Sebelius*, No. 06-cv-2226 (DLI), 2010 WL 1037250, at *6 (E.D.N.Y. Jan. 21, 2010) (same); s*ee also* 5 U.S.C. § 704 (providing for review of agency actions only where there is "no other adequate remedy in a court"). Even if the APA did apply, there is no evidence to suggest that the ALJ's decision was "unlawfully withheld or unreasonably delayed"; "arbitrary and capricious, [an] abuse of discretion, [or] not in accordance with law"; "in excess of statutory jurisdiction, authority, or limitations or short of statutory right"; or "without observance of procedure required by law." (Compl. at 7-8.)

To the extent Plaintiff may attempt to challenge the ALJ's decision pursuant to 42 U.S.C. § 405(g) based on the argument that it was not supported by substantial evidence, that argument would also fail. ALJ Butler's decision was based on the LCD that was then in effect, to which the ALJ owed deference; the fact that even the new LCD would not cover Plaintiff's recurrent GBM; and the fact that Plaintiff used his device at a rate significantly below what was recommended. (CAR 67-74.) This is "such relevant evidence as a reasonable mind might accept as adequate to support" the conclusion that coverage was not warranted. *Richardson*, 402 U.S. at 401.

CONCLUSION

For the reasons above, the Secretary respectfully requests that the Court grant his motion for summary judgment and dismiss Plaintiff's claims with prejudice.

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New York, New York

Respectfully submitted,

AUDREY STRAUSS
Acting United States Attorney for the
Southern District of New York

By: */s/ Rachael Doud*

RACHAEL DOUD
Assistant United States Attorney
86 Chambers Street, Third Floor
New York, New York 10007
Telephone: (212) 637-2697
Facsimile: (212) 637-2717
E-mail: rachael.doud@usdoj.gov